

FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS

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FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS¹

I. INTRODUCTION

The Federal Trade Commission is a law enforcement agency charged by Congress with protecting the public against anticompetitive behavior and deceptive and unfair trade practices. The FTC's antitrust arm, the Bureau of Competition, is responsible for investigating and prosecuting "unfair methods of competition" which violate the FTC Act. The FTC shares with the Department of Justice responsibility for prosecuting violations of the Clayton Act.

When litigation becomes necessary, many of the FTC's adjudicative matters are conducted in administrative adjudication before an FTC Administrative Law Judge. This provides the opportunity for matters raising complex legal and economic issues to be heard, in the first instance, in a forum specially suited for dealing with such matters. Appeals from Commission decisions are taken directly to the federal courts of appeal. The Commission also has the authority to seek a preliminary injunction in federal district court whenever the Commission has reason to believe that a party is violating, or is about to violate, any provision of law enforced by the FTC. Such preliminary injunctions are intended to preserve the status quo, or to prevent further consumer harm, pending administrative adjudication before the Commission. Additionally, the Commission has the authority to seek a permanent injunction in federal district court in a "proper case" pursuant to section 13(b) of the FTC Act.

In the mid-1970's, the FTC formed a division within the Bureau of Competition to investigate potential antitrust violations involving health care. The Health Care Services and Products Division consists of approximately thirty-five lawyers and investigators who work exclusively on health care antitrust matters. Health Care Services and Products Division staff also work with staff in the FTC's seven regional offices on health care matters. FTC cases involving health care services and products are summarized below.² The Commission and its staff have also responded to numerous requests for

¹ This summary has been prepared by the FTC Health Care Services and Products Division staff, and has not been reviewed or approved by the Commission or the Bureau of Competition. Section III describes FTC enforcement involving mergers in the pharmaceutical industry, which are primarily conducted by the Mergers I Division of the Bureau of Competition. Section IV describes FTC enforcement involving hospital mergers, which are now primarily conducted by the Bureau's Merger Litigation Task Force.

² Commission complaints and orders issued since March, 1996, are available at the FTC's website at http://www.ftc.gov.

guidance from health care industry participants through, among other things, the advisory opinion letter process, and through the issuance of statements on enforcement policy.³

For further information about matters handled by the FTC's Health Care Services and Products Division, or to lodge complaints about suspected antitrust violations, please write, call, or fax this office as follows:

Mailing Address: Health Care Services and Products Division

Bureau of Competition Federal Trade Commission Washington, DC 20580

Telephone Number: 202-326-2756 Fax Number: 202-326-3384

For further information about pharmaceutical merger matters handled by the FTC's Mergers I Division, please write, call, or fax the Mergers I Division as follows:

Mailing Address: Mergers I Division

Bureau of Competition Federal Trade Commission Washington, DC 20580

Telephone Number: 202-326-2682 Fax Number: 202-326-2655

For further information about hospital merger matters handled by the FTC's Merger Litigation Task Force, please write, call, or fax the Merger Litigation Task Force as follows:

Mailing Address: Merger Litigation Task Force

Bureau of Competition Federal Trade Commission Washington, DC 20580

³ Information regarding advisory opinions is set forth in the <u>Topic and Yearly Indices of Health Care</u> <u>Advisory Opinions by Commission and by Staff</u>. The index, and the advisory opinions issued since October, 1993, are available at the FTC's website at http://www.ftc.gov.

Telephone Number: (202) 326-2769 or (202)-326-2214

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II. CONDUCT INVOLVING HEALTH CARE SERVICES AND PRODUCTS

A. Monopolization

1. Bristol-Myers Squibb Company, FTC File Nos. 0010221, 0110046 and 0210181 (proposed consent order issued March 6, 2003) (FTC Commission Actions: March 7, 2003 (www.ftc.gov)). The Commission charged in its complaint that Bristol engaged in a pattern of anticompetitive activity over the past decade in order to delay generic competition and maintain its monopoly over three highly profitable branded drugs with total net annual sales of two billion dollars. As a result of Bristol's illegal conduct, consumers paid hundreds of millions of dollars in additional costs for these prescription drugs. The drugs named in the complaint were the antianxiety drug, BuSpar, and two anti-cancer drugs, Taxol and Platinol. The pattern of illegal activity involved misusing regulations set up by Congress to hasten the approval of generic drugs, misleading the FDA and the U.S. Patent and Trademark Office in order to protect patents on these branded drugs, and filing baseless patent infringement lawsuits against would be generic competitors. As detailed in the complaint, the anticompetitive activities involving BuSpar included: paying a would-be generic competitor \$72.5 million to settle patent litigation, thereby preventing the introduction of a generic BuSpar; filing false information with the FDA in order to list a patent in the Orange Book, thereby automatically obtaining additional 30-month stays; and filing baseless patent infringement suits against potential generic competitors. The complaint alleged that Bristol engaged in similar types of activities with Taxol, a chemotherapy drug originally developed and funded by the National Cancer Institute, which had given Bristol exclusive marketing rights. This conduct including improperly listing three patents in the Orange book, filing misrepresentative statements with the FDA, and entering into an unlawful agreement with a generic competitor in order to obtain an additional 30-month stay on FDA approval of generic Taxol. Similarly, according to the complaint, Bristol engaged in the same type of unlawful activities involving another chemotherapy drug, Platinol, that also included wrongfully submitting a patent for listing in the Orange Book, and filing patent infringement lawsuits against each of four potential generic entrants, resulting in the delay of a generic Platinol.

The proposed order contains general prohibitions concerning conduct relating to Orange Book listings (detailed in the Commission's recent study, *Generic Drug Entry Prior to Patent Expiration*), enforcement of patents, and the settlement of patent litigation when that conduct is designed to delay or prevent generic competition. For example Bristol is prohibited from late listing patents after competitors have filed applications with the FDA for generic entry. The order also contains prohibitions relating specifically to the listing and enforcement of patents relating to Taxol and BuSpar, including listing any patent in the Orange Book relating to

- products with the same active ingredient, or taking any action that would trigger an additional 30-month statutory stay on final FDA approval of a generic form of Taxol or BuSpar (the order does not provide specific relief for Platinol because a court held the only unexpired patent on Platinol was invalid).
- 2. **Biovail Corporation**, C-4060 (consent order issued October 2, 2002) (FTC Commission Actions: October 4, 2002 (www.ftc.gov)). The complaint charged that Biovail illegally acquired the exclusive license to a drug patent in order to prevent generic competition from ending its monopoly in the antihypertension drug Tiazac. Biovail then wrongfully listed the acquired patent as claiming Tiazac in the FDA's Orange Book in order to maintain its monopoly. As a result of the Orange Book listing and other conduct, including making a misleading statement to the FDA during the regulatory process, the complaint alleged that Biovail sought to illegally delay the entry of generic Tiazac by gaining a second 30-month stay on generic entry through patent infringement litigation. The order requires Biovail to divest part of the exclusive rights of the acquired patent back to DOV Pharmaceuticals, the original owner. In addition, the order prohibits Biovail from taking any action that would trigger an additional statutory stay on final FDA approval of a generic form of Tiazac. The order also prohibits Biovail from wrongfully listing any patents in the Orange Book.

B. Agreements Not to Compete

- 1. **Bristol-Myers Squibb Company** (See Section I A for citation and annotation.)
- 2. **Biovail Corporation/Elan Corporation**, C-4057, (consent order issued August 15, 2002) (FTC Commission Actions: August 20, 2002 (www.ftc.gov)). According to the complaint, Biovail and Elan were the only companies with FDA approval to market 30 mg and 60 mg generic Adalat. Elan was the first to file for FDA approval on the 30 mg dosage, and Biovail was the first to file for FDA approval on the 60 mg dosage. Pursuant to the Hatch-Waxman Act, Elan qualified for 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail qualified for 180 days of exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the dosage for which the other was the first filer. Prior to generic entry, Bayer's sales of the branded form of the 30 mg and 60 mg products were in excess of \$270 million a year. In October 1999, Biovail and Elan entered into an agreement involving these products. In exchange for specified payments, Elan appointed Biovail as the exclusive distributor of Elan's 30 mg and 60 mg products and allowed Biovail to profit from the sale of both products. Biovail appointed Teva Pharmaceuticals, Inc. to sub-distribute Elan's 30 mg product in the United States, and agreed to appoint another firm to sub-distribute Elan's 60 mg product. The agreement had a minimum term of 15 years.

In March 2000, the FDA gave final approval to Elan's 30 mg product and Elan, under its agreement with Biovail, entered the market with its 30 mg product through Biovail. In December 2000, the FDA gave final approval to Biovail's 60 mg product and Biovail entered the market with that product. Also in December 2000, the FDA gave final approval to

Biovail's 30 mg product, but Biovail never launched that product. Similarly, in October 2001, the FDA gave final approval to Elan's 60 mg product, but Elan never launched that product. Thus, Elan had a monopoly over 30 mg generic Adalat, the profits from which it shared with Biovail; Biovail had a monopoly over 60 mg generic Adalat, having paid Elan a multi-million dollar royalty; and neither launched a product in competition with the other's dosage form.

The order requires Biovail and Elan to terminate their agreement immediately, and prohibits them from entering similar agreements in the future. It requires them to use best efforts to effect independent launches of both 30 mg and both 60 mg generic Adalat products as promptly as possible, and contains an interim supply arrangement to ensure that consumers continue to have access to at least one 30 mg and one 60 mg product while Biovail and Elan unwind their agreement. In addition, the order contains strict reporting and notice requirements intended to assist the Commission in monitoring compliance with the order.

3. FTC v. Schering Plough Corporation, et. al., D. 9297 (initial decision issued June 27, 2002) (FTC Commission Actions: April 2, 2001, April 5, 2002, July 2, 2002 (www.ftc.gov)). The complaint alleged that Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products Corporation entered into anticompetitive agreements in which Schering paid Upsher and American Home Products millions of dollars to delay launching a competitive generic alternative to K-Dur 20, an extended-release potassium chloride supplement manufactured by Schering. Schering sued Upsher, a generic drug manufacturer, for patent infringement after Upsher sought FDA approval to manufacture and distribute Klor Con M20, a generic version of K-Dur 20. The complaint alleged that Schering and Upsher reached an agreement in 1997 to settle the patent infringement lawsuit, whereby Schering paid Upsher \$60 million dollars not to market any generic version of K-Dur 20 until September, 2001. Under the agreement, Schering received licenses to market five of Upsher's products but, the complaint charged, the value of the licenses had little relation to the \$60 million dollar payment, and the effect of the agreement was to ensure that no other company's generic K-Dur 20 could obtain FDA approval and enter the market during the term of the agreement.

The complaint also alleged that Schering agreed to pay ESI Lederle, Inc., a division of American Home Products, up to \$30 million to delay marketing its generic version of K-Dur 20. As part of the agreement, ESI also granted Schering a license to two of its generic products. Schering sued ESI for patent infringement after ESI sought FDA approval to manufacture and distribute its generic version of K-Dur 20. As part of the patent infringement litigation settlement, ESI agreed, in exchange for the payments, not to market any generic version of K-Dur 20, until January 2004, and to market only one generic version between January 2004 and September 2006 when Schering's patent expired. ESI also agreed not to prepare, or help any other firm prepare, bioequivalence studies necessary for FDA approval of an application for a generic version of K-Dur 20 until September 2006. The complaint alleged that the payment was designed to delay the entry of a generic version of K-Dur 20, and was

not based on the value of the licenses.

American Home Products agreed to a proposed consent agreement and its matter was withdrawn from adjudication. On April 2, 2002, the Commission approved a final order settling the charges against American Home Products. The order prohibits American Home Products, whether acting as a brand or generic competitor, from entering into agreements in which a generic company agrees not to market its drug or enter the market with a non-infringing generic drug. An administrative trial as to respondents Schering and Upsher was held from January 23 through March 22, 2002, before Judge Chappell. In an initial decision issued on June 27, 2002, Judge Chappell dismissed the complaint. According to the decision, Commission staff failed to prove its product market, and the payments made to Upsher and American Home Products were not in exchange for their agreement as to an entry date. Judge Chappell also found that the relevant product market was all oral potassium supplements, that Schering did not have monopoly power in that market, and that the agreements did not delay the entry of generic competition. On July 8, 2002, complaint counsel filed a notice of appeal. Oral argument before the Commission was heard on January 7, 2003.

- 4. FTC v. Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp., D. 9293 (consent order issued May 8, 2001) (FTC Commission Actions: May 11, 2001 (www.ftc.gov)) The complaint alleged that Hoechst and Andrx entered into an agreement in which Andrx was paid millions of dollars to delay bringing to market a competitive generic alternative to Cardizem CD. Andrx, a generic drug manufacturer, was the first to file for FDA approval to market its generic version of Hoechst's brand name hypertension and angina drug, Cardizem CD, but was sued by Hoechst for patent infringement. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180 day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic drug could obtain FDA approval and enter the market during the term of the agreement. Under the agreement, according to the complaint, Andrx agreed not to market its product when it received FDA approval, not to give up or relinquish its 180-day exclusivity right, and not to market a non-infringing generic version of Cardizem CD during the ongoing patent litigation. The order prohibits respondents from entering into agreements in which the first generic company to file an ANDA agrees: 1) not to relinquish its rights to the 180-day exclusivity period; and 2) not to develop or market a non-infringing generic drug product. The order also requires Hoechst and Andrx to notify the Commission, and obtain court approval, before entering into any agreements involving payments to a generic company in which the generic company temporarily refrains from bringing a generic drug to market.
- 5. <u>Abbott Laboratories and Geneva Pharmaceuticals, Inc.</u> C-3945, C-3946 (consent orders issued May 22, 2000) (FTC Commission Actions: May 26, 2000 (<u>www.ftc.gov</u>)). The

complaint alleged that Abbott paid Geneva \$4.5 million per month to delay bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin. Geneva, a generic drug manufacturer, sought and received FDA approval to market its generic capsule version. After Geneva received FDA approval, Abbott and Geneva reached an agreement whereby Geneva would not bring a generic version of Hytrin to market during the ongoing patent litigation on Geneva's tablet version of Hytrin in exchange for the \$4.5 million monthly payment, an amount which exceeded the amount Abbott estimated Geneva would have received if it actually marketed the generic drug. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180-day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic Hytrin could obtain FDA approval and enter the market during the term of the agreement. The consent orders prohibit Abbott and Geneva from entering into agreements in which a generic company agrees with the brand drug manufacturer to 1) give up or transfer its Hatch-Waxman 180-day exclusivity rights, or 2) not enter the market with a non-infringing product. In addition, the orders require that agreements involving payments to a generic company to stay off the market during the pendency of patent litigation be approved by the court with notice to the Commission. Geneva was also required to waive its right to a 180-day exclusivity period for its generic tablet, so other generic tablets could immediately enter the market. In a statement accompanying the consent orders, the Commission warned that in the future it will consider its entire range of remedies in enforcement actions against similar arrangements, including seeking disgorgement of illegally obtained profits.

C. Agreements on Price or Price-Related Terms

1. Professionals in Women's Care, C-4063, (consent order issued October 8, 2002) (FTC Commission Actions: October 11, 2002 (www.ftc.gov)). The complaint charged that eight competing OB/GYN practices in the Denver area and their agent organized more than 80 OB/GYNs, under the name Professionals in Women's Care, to collectively fix prices, to engage in collective contract negotiations with payers, and to refuse to deal with payers. By terminating or threatening to terminate their contracts with payers if their demands for higher fees were not met, the physicians were able to pressure the payers into offering contracts with significantly higher fees. According to the complaint, the organization was formed to negotiate contracts with payers, but it was not clinically integrated and did not follow a messenger model arrangement with its agent. The order forbids the respondents from engaging in certain conduct, including agreeing to negotiate on behalf of the organization with payers, agreeing to refuse to deal with payers, and agreeing on any terms for dealing with payers. The order allows the physicians to operate a "qualified risk-sharing joint arrangement" or "qualified clinically integrated joint arrangement." For a period of three years, the order also prohibits the agent from negotiating with any payer on behalf of the physicians, or advising the physicians on their dealings with any payer.

- 2. System Health Providers, C-4064, (consent order issued October 24, 2002) (FTC Commission Actions: November 1, 2002 (www.ftc.gov)). The complaint alleged that System Health Providers (SHP) and its parent corporation, Genesis Physician's Group, Inc., a 1250 member physician group, restrained competition in the provision of physician services in the Dallas-Fort Worth area. As a result of this conduct, payers found it difficult to establish a viable physician network unless they paid the fees demanded by SHP. According to the complaint, the respondents collectively agreed to negotiate fees and other significant terms in payers' contracts, refused to deal individually with health plans except through SHP, and refused to messenger payer offers to members that did not conform to SHP's standards for contracts. The complaint also alleged that the group was not clinically integrated and did not participate in any financial risk-sharing. The order forbids the respondents from engaging in certain conduct, including agreeing to negotiate on behalf of the group with payers, agreeing to refuse to deal with payers, and agreeing on any terms for dealing with payers. The order also prohibits the respondents from exchanging information among area physicians concerning negotiations with any health plan regarding the terms, including price, on which the physician is willing to deal. The order allows the physicians to operate a "qualified risk-sharing joint arrangement" or a "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.
- Obstetrics and Gynecology Medical Corporation of Napa Valley, C-4048 (consent 3. order issued May 14, 2002) (FTC Commission Actions: May 17, 2002 (www.ftc.gov)). The complaint charged that OGMC, a non-risk-bearing independent practice group comprising the majority of obstetricians and gynecologists in Napa County, California, and six physician shareholders of OGMC agreed to fix prices and other terms on which they would deal with third party payers, and then collectively refused to deal with third party payers. According to the complaint, members of OGMC resigned from Napa Valley Physicians, a risk-sharing IPA that contracted with payers, because of dissatisfaction with the level of reimbursement obtained through Napa Valley Physicians. OGMC then boycotted Napa Valley Physicians and payers in order to increase reimbursement. As a result, the complaint charged, Napa Valley Physicians was forced to disband and some HMOs discontinued service in Napa County. The order requires the dissolution of OGMC and forbids the respondents from engaging in certain conduct including agreeing to negotiate on behalf of physicians with payers, agreeing to refuse to deal with payers, and agreeing on any terms for dealing with payers. The order allows the respondents to operate a "qualified risk-sharing joint arrangement" or "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.
- 4. **Physicians Integrated Services of Denver, Inc.** C-4054 (consent order issued July 16, 2002) (FTC Commission Actions: July 19, 2002 (www.ftc.gov)). The complaint charged that

an organization composed of 41 primary care physicians in the Denver area, the organization's president, and the group's non-physician agent, collectively agreed to fix prices and other terms they would accept from payers, and then terminated or threatened to terminate their contracts with payers if their demands for significantly higher fees were not met. According to the complaint, the organization was formed to negotiate contracts with payers, but was not clinically integrated and did not follow a messenger model arrangement with its agent. The order forbids the respondents from engaging in certain conduct, including agreeing to negotiate on behalf of the organization with payers, agreeing to refuse to deal with payers, and agreeing on any terms for dealing with payers. The order allows the physicians to operate any "qualified risk-sharing joint arrangement" or "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. For a period of three years, the order also prohibits the agent from negotiating with any payer on behalf of the physicians, or advising the physicians on their dealings with any payer.

- 5. Aurora Associated Primary Care Physicians, L.L.C. C-4055 (consent order issued July 16, 2002) (FTC Commission Actions: July 19, 2002 (www.ftc.gov)). The complaint charged that an organization composed of 45 primary care physicians in the Aurora, Colorado area, two physician leaders, and the group's non-physician agent collectively agreed to fix prices and other terms they would accept from payers, and then terminated or threatened to terminate their contracts with payers if their demands for significantly higher fees were not met. The agent is the same person named in Physicians Integrated Services of Denver, Inc., discussed above. According to the complaint, the organization was formed to negotiate contracts with payers but was not clinically integrated and did not follow a messenger model arrangement with its agent. The order forbids the physicians from engaging in certain conduct, including agreeing to negotiate on behalf of the group with payers, agreeing to refuse to deal with payers, and agreeing on any terms for dealing with payers. The order allows the physicians to operate a "qualified risk-sharing joint arrangement" or "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. For a period of three years, the order also prohibits the agent from negotiating with any payer on behalf of the physicians, or advising the physicians on their dealings with any payer.
- 6. Alaska Healthcare Network, Inc., C-4007 (consent order issued April 25, 2001) (FTC Commission Actions: April 27, 2001 (www.ftc.gov)). The complaint alleged that the Alaska Healthcare Network, Inc., an association of 86 physicians practicing in the Fairbanks, Alaska area, restrained competition among physicians, and blocked or delayed the entry of health care plans into the Fairbanks area. The AHN included approximately 63% of all physicians in full-time, year-round private practice in Fairbanks. The complaint further alleged that, acting as the de facto collective bargaining agent for its members, AHN fixed prices and other terms when contracting with HMOs and other healthcare payers, refused to deal with payers except on collectively agreed-upon terms, and encouraged its members not to deal with any health plan in

any manner except through AHN. The consent order prohibits AHN from: 1) negotiating or refusing to deal with health plans; 2) determining the terms upon which physicians deal with health plans; and, 3) restricting the ability of physicians to deal with any health plan, whether on an individual basis or through any other arrangement. The order also imposes a structural remedy for a period of five years, which requires that if AHN operates a qualified risk-sharing or clinically-integrated joint arrangement, AHN participating physicians can constitute no more than 30% of Fairbanks physicians in five medical specialties. Also, when offering the services of its physicians through any other arrangement permitted by the order, AHN's participating physicians may constitute no more than 50% of Fairbanks physicians in those specialties. In a separate statement, Commissioners Swindle and Leary disagreed with the need for the structural remedy requirement because of the small size of the Fairbanks market.

- 7. Texas Surgeons, P.A., C-3944 (consent order issued May 18, 2000) (FTC Commission Actions: May 23, 2000 (www.ftc.gov)). The complaint alleged that Texas Surgeons, P.A., an independent physician association, restrained competition among general surgeons in the Austin, Texas area, resulting in more than \$1,000,000 in increased costs for surgical services in 1998 and 1999. According to the complaint, the IPA collectively refused to deal with two health plans, terminated contracts with Blue Cross of Texas, and threatened to terminate contracts with United HealthCare of Texas if the payer did not comply with the association's demand for rate increases. Both plans increased their rates in response to the IPA's demands. The order prohibits the IPA from 1) negotiating on behalf of any physician with health plans, 2) refusing to deal or threatening to refuse to deal with health plans, 3) determining the terms on which its members deal with health plans, and 4) restricting the ability of any physicians to deal with any payer or provider individually or through any other arrangement. The order also prohibits the respondent from exchanging information among Austin area physicians concerning negotiations with any health plan regarding reimbursement terms, or any physician's intent to refuse to deal with any health plan. The order does allow the IPA to operate any "qualified risk-sharing joint arrangement" or any "qualified clinically integrated joint arrangement" as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. In 1999 the Texas legislature enacted a statue that permits the Texas Attorney General to approve, under certain conditions, joint negotiations between health plans and groups of competing physicians. Because it is unclear whether the IPA's conduct in this matter would be approved by the Texas Attorney General, the order allows the IPA to engage in future conduct that is approved and supervised by the State of Texas, if that conduct is protected from liability under the federal antitrust laws under the "state action" doctrine.
- 8. <u>Colegio de Cirujanos Dentistas de Puerto Rico</u>, C-3953 (consent order issued June 12, 2000) (FTC Commission Actions: June 16, 2000 (www.ftc.gov). The complaint charged that an association of approximately 1800 dentists, acting as the collective bargaining agent for its members, fixed prices, boycotted payers to obtain higher reimbursement rates, and restrained

truthful advertising by its members. The association, comprising almost all dentists practicing in Puerto Rico, negotiated with numerous payers about fees and set the terms its members would accept from the payers. The complaint also alleged that the association used its Code of Ethics to ban truthful advertising by dentists who advertised their willingness to accept patients from neighboring areas where dentists were conducting a boycott of the Reform, a government program to provide medical services to the indigent. The order prohibits the association from negotiating on behalf of any dentists with payers or providers, refusing to deal with or boycotting payers, determining the terms upon which dentists will deal with providers, and restricting or interfering with truthful advertising or solicitation concerning dental services.

- Wisconsin Chiropractic Association C-3943 (consent order issued May 18, 2000) (FTC 9. Commission Actions: May 23, 2000 (www.ftc.gov)). The complaint alleged that the Wisconsin Chiropractic Association and its executive director conspired to boycott third-party payers to obtain higher reimbursement rates, thereby increasing prices for chiropractic services. The Wisconsin Chiropractic Association has 900 members, and represents about 90% of the chiropractors licensed in the state. According to the complaint, the association, in response to the introduction of new billing codes by private insurers and the federal government, advised its members to collectively raise their prices to specific levels, circulated fee schedules to coordinate pricing among its members, advised members to discuss contract offers to improve their bargaining position with payers, and assisted in boycotts of two payers to obtain higher reimbursement rates. The order prohibits the association from fixing prices or encouraging others to fix prices for chiropractic services, boycotting any payer, or negotiating on behalf of any chiropractor or group of chiropractors. The order also prohibits the association from initiating, conducting, or distributing any fee surveys for healthcare goods or services prior to December 31, 2001. In addition, for five years thereafter, the WCA may conduct or distribute fee surveys only if the surveys conform to the safe harbor provisions regarding fee surveys contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.
- Michael T. Berkley, D.C. and Mark A. Cassellius, D.C., C-3936, (consent order issued April 11, 2000) (FTC Commission Actions: April 18, 2000 (www.ftc.gov)). The complaint alleged that two chiropractors conspired to fix prices for chiropractic services in the La Crosse, Wisconsin area, and boycotted the Gundersen Lutheran Health Plan to obtain higher reimbursement for chiropractic services. As a result of the boycott, Gundersen increased its reimbursement rates by 20%. The proposed order is similar to the Wisconsin Chiropractic Association order (discussed above), and prohibits Drs. Berkley and Cassellius from fixing prices for chiropractic services, engaging in collective negotiations on behalf of other chiropractors, and orchestrating concerted refusals to deal. The order does allow the chiropractors to engage in conduct, including collectively determining reimbursement and other terms of contracts with payers, that is reasonably necessary to operate a "qualified risk-sharing joint arrangement," or a "qualified clinically integrated joint arrangement," as reflected in the

- North Lake Tahoe Medical Group, Inc., C-3885 (consent order issued July 21, 1999) 11. (FTC Commission Actions: August 2, 1999 (www.ftc.gov)). The complaint alleged that North Lake Tahoe Medical Group, Inc. (Tahoe IPA), an independent physician association, restrained competition among physicians and delayed the entry of managed care in the Lake Tahoe Basin in California. Tahoe IPA, based in Truckee, California, is composed of ninetyone physicians comprising 70% of the physicians practicing in the Lake Tahoe area. The complaint further alleged that the IPA conspired to fix prices, engaged in collective negotiations over prices with payers, and refused to deal with Blue Shield of California and other third party payers when it did not comply with the Tahoe IPA's plans. The order prohibits the IPA from 1) engaging in collective negotiations on behalf of its members, 2) orchestrating concerted refusals to deal, 3) fixing prices, or any other terms, on which its members deal, and 4) restricting the ability of any physician to deal with any payer or provider individually or through any arrangement outside of Tahoe IPA. The order also requires Tahoe IPA to terminate the membership of physicians who refused to deal (or gave notice of their intent to refuse to deal) with Blue Shield, unless the physicians make a good faith effort to reparticipate and continue to participate in Blue Shield for a period of six months. In a separate statement, Commissioner Swindle disagreed with the need for the termination requirement because market incentives should result in reparticipation by the physicians in Blue Shield. The order does allow the IPA to operate any "qualified risk-sharing joint arrangement," or, upon prior notice to the Commission, any "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.
- 12. Mesa County Physicians Independent Practice Association, Inc., 127 F.T.C. 564 (1999) (consent order). The Commission issued a revised complaint and final order against the Mesa County Physicians Independent Practice Association, Inc., an organization whose members comprise 85% of all physicians and 90% of the primary care physicians in Mesa County, Colorado. According to the complaint, the IPA acted to restrain trade by combining to fix prices and other competitively significant terms of dealing with payers, and collectively refused to deal with third party payers, thereby hindering the development of alternative health care financing and delivery systems in Mesa County. The complaint alleged that the IPA, through its alliance with the Rocky Mountain Health Maintenance Organization, created a substantial obstacle to the ability of other payers to contract with a physician panel in Mesa County. The complaint also alleged that the IPA's Contract Review Committee negotiated collectively on behalf of the IPA's members with several third party payers, using an IPA Board-approved set of guidelines and fee schedule, and that a similar organization formed after the proposed consent order was issued in 1998 engaged in the same conduct. The order prohibits the Mesa County IPA from: 1) engaging in collective negotiations on behalf of its members; 2) collectively refusing to contract with third party payers; 3) acting as the exclusive bargaining agent for its

members; 4) restricting its members from dealing with third party payers through an entity other than the IPA; 5) coordinating the terms of contracts with third-party payers with other physician groups in Mesa County or in any county contiguous to Mesa County; 6) exchanging information among physicians about the terms upon which physicians are willing to deal with third-party payers; and, 7) encouraging other physicians to engage in activities prohibited by the order. The order also requires the Mesa IPA to abolish its Contract Review Committee, and prohibits the IPA from employing any person or participating physician who is conducting payer contract review. The order, however, allows the respondent to engage in 1) any "qualified clinically integrated joint arrangement" (with prior notice to the Commission), and 2) conduct that is reasonably necessary to operate any "qualified risk-sharing joint arrangement" as set forth in the 1996 DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care.

- Asociacion de Farmacias Region de Arecibo, 127 F.T.C. 266 (1999) (consent order). 13. The complaint alleged that an association, composed of approximately 125 pharmacies in northern Puerto Rico, fixed the terms and conditions, including fixing prices, of dealing with third party payers, and threatened to withhold services from a government program to provide health care services for indigent patients. The association was formed in 1994 as a vehicle to negotiate with health plans. According to the complaint, in January 1995, the association refused to contract with Triple-S, the payer for the reform program in northern Puerto Rico, until Triple-S raised the fees paid to the association's members. Furthermore, in March 1996, the association threatened to withhold its members' services unless Triple-S rescinded a new fee schedule calling for lower reimbursement fees for the pharmacies. Triple-S acceded to the association's demands and increased fees by 22%. The order prohibits the association from negotiating on behalf of any pharmacies with any payer or provider, jointly boycotting or refusing to deal with third party payers, restricting the ability of pharmacies to deal with payers individually, or determining the terms or conditions for dealing with third party payers. The order does allow the association to operate any "qualified risk-sharing joint arrangement" or, upon prior notice to the Commission, any "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.
- 14. **Ernesto L. Ramirez Torres, D.M.D., et al.**, 127 F.T.C. 134 (1999) (consent order). The complaint alleged that a group of dentists, comprising a majority of the dentists in Juan Diaz, Coamo, and Santa Isabel, Puerto Rico, fixed prices and engaged in an illegal boycott of a government program to provide dental care for indigent patients. According to the complaint, the dentists threatened a boycott of the reform program if they were not reimbursed at certain prices, and then boycotted the program. After several months, the dentists' price demands were met and they agreed to participate in the program. The order prohibits the dentists from jointly boycotting or refusing to deal with third party payers, or collectively determining any terms or conditions for dealing with third party payers. The order does allow the dentists to operate any "qualified risk-sharing joint arrangement" or, upon notice to the Commission, any

"qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

- FTC v. Mylan Laboratories et al., 62 F. Supp. 2d 25 (D.D.C. 1999) (FTC Commission 15. Actions: November 29, 2000 (www.ftc.gov)). In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged Mylan Laboratories and three other companies, Profarmaco S.R.L., Cambrex Corporation, and Gyma Laboratories, with restraint of trade and conspiracy to monopolize the markets for two generic anti-anxiety drugs, lorazepam and clorazepate. The complaint also charged Mylan with monopolization and attempted monopolization of those markets. Thirty four state Attorneys General filed a similar complaint in U.S. District Court. According to the FTC's complaint, Mylan, the nation's second largest generic drug manufacturer, sought to restrain competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and clorazepate tablets, thereby allowing Mylan to dramatically increase the price of lorazepam and clorazepate tablets. On July 7, 1999, the court denied defendants' motions to dismiss the FTC complaint, finding that § 13(b) of the FTC Act allows the Commission to seek permanent injunctive relief for violations of "any provision of law" enforced by the FTC, and allows the Commission to seek monetary remedies such as the disgorgement of profits. On November 29, 2000, the Commission approved a proposed settlement, subject to approval by the federal district court, under which Mylan agreed to pay \$100 million for distribution to injured consumers and state agencies. The defendants also agreed to an injunction barring them from entering into similar unlawful conduct in the future. Fifty states and the District of Columbia also approved the agreement. In a separate statement, Commissioner Leary dissented regarding the financial aspects of the settlement because of his concern that it sets an undesirable precedent for use of the Section 13(b) remedy in federal and state antitrust enforcement, and conflicts with the holding in Illinois Brick concerning the ability of indirect purchasers to claim damages. In a separate statement, Commissioners Pitofsky, Anthony, and Thompson agreed with the need to use discretion in seeking disgorgement in future antitrust cases, but stated that the decision to seek disgorgement in this case was appropriate and consistent with policy considerations towards indirect purchasers raised by Illinois Brick. On February 9, 2001, the court entered the Stipulated Permanent Injunction agreed to by the parties. On February 1, 2002, the court granted final approval of the settlement agreement and distribution plan under which Mylan was required to place \$100 million into an escrow account for disbursement to purchasers of lorazepam and/or clorazepate during the time period covered by the settlement.
- 16. M.D. Physicians of Southwest Louisiana Inc., 126 F.T.C. 219 (1998) (consent order). The complaint charged that M.D. Physicians of Southwest Louisiana, Inc., a physician group comprising a majority of the physicians in the Lake Charles area of Louisiana, fixed the prices and other terms on which it would deal with third party payers, collectively refused to deal with

third party payers, and conspired to obstruct the entry of managed care. According to the complaint, the group was formed in 1987 as a vehicle for its members to deal concertedly with the entry of managed care, and until 1994, the members of MDP dealt with third party payers only through the group. As a result of this conduct, the complaint alleged, MDP restrained competition among physicians, increased the prices that consumers pay for physician services and medical insurance coverage, and deprived consumers of the benefits of managed care. The consent order prohibits MDP from engaging in collective negotiations on behalf of its members, orchestrating concerted refusals to deal, fixing prices or terms on which its members deal, or encouraging or pressuring others to engage in any activities prohibited by the order. The order does allow MDP to operate any "qualified risk-sharing joint arrangement" or, upon prior notice to the Commission, any "qualified clinically integrated joint arrangement," as reflected in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

- 17. <u>Institutional Pharmacy Network</u>, 126 F.T.C. 138 (1998) (consent order). The complaint alleged that five institutional pharmacies unlawfully fixed prices and restrained competition among institutional pharmacies in Oregon, leading to higher reimbursement levels for serving Medicaid patients in Oregon long-term care institutions. The five pharmacies, Evergreen Pharmaceutical, Inc., NCS Healthcare of Oregon, Inc., NCS Healthcare of Washington, Inc., United Professional Companies, Inc., and White, Mack and Wart, Inc. (which provide institutional pharmacy services for 80% of those patients in Oregon receiving such services) competed to provide prescription drugs and services to long term care institutions. According to the complaint, the pharmacies formed IPN to offer their services collectively and maximize their leverage in bargaining over reimbursement rates, but did not share risk or provide new or efficient services. The order prohibits IPN and the institutional pharmacy respondents from entering into similar price fixing arrangements. The order, however, allows the respondents to engage in 1) any "qualified clinically integrated joint arrangement" (with prior notice to the Commission), and 2) conduct that is reasonable necessary to operate any "qualified risksharing joint arrangement" as set forth in the DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care.
- 18. <u>Urological Stone Surgeons, Inc.</u>, 125 F.T.C. 513 (1998) (consent order). The complaint charged that three companies (Urological Stone Surgeons, Inc., Stone Centers of America, L.L.C., and Urological Services, Ltd.) and two doctors providing lithotripsy services at Parkside Kidney Stone Centers illegally fixed prices for professional urologist services for lithotripsy procedures in the Chicago metropolitan area. Urologists using the Parkside facility account for approximately 65% of urologists in the area. The complaint alleged that the respondents agreed to use a common billing agent (Urological Services, Ltd.), established a uniform fee for lithotripsy professional services, prepared and distributed fee schedules for lithotripsy professional services at Parkside, and billed a uniform amount either from the fee schedule or an amount negotiated on behalf of all urologists at Parkside. The complaint also

alleged that the billing agent contracted with third party payers based on a uniform percentage discount off the urologist's charge for professional services, or a uniform global fee that included professional services, charges for the lithotripsy machine, and anesthesiology services. According to the complaint, the collective setting of fees for lithotripsy services was not reasonably necessary to achieve efficiencies from the legitimate joint ownership and operation of the lithotripsy machines, nor were the urologists sufficiently integrated so as to justify the agreement to fix prices for lithotripsy professional services. The consent order prohibits the respondents from fixing prices, discounts, or other terms of sale or contract for lithotripsy professional services, requires the respondents to terminate third-party payer contracts that include the challenged fees at contract-renewal time or upon written request of the payer, and requires the respondents to notify the FTC at least 45 days before forming or participating in an integrated joint venture to provide lithotripsy professional services.

- 19. College of Physicians-Surgeons of Puerto Rico, FTC File No. 9710011, Civil No. 97-2466-HL (District of Puerto Rico) (October 2, 1997). The Federal Trade Commission and the Commonwealth of Puerto Rico filed a final order, stipulated permanent injunction, and complaint in the U.S. District Court in Puerto Rico against the College of Physician-Surgeons of Puerto Rico (comprised of 8,000 physicians in Puerto Rico), and three physician independent practice associations. The complaint charged that the defendants attempted to coerce the Puerto Rican government into recognizing the College as the exclusive bargaining agent for all physicians in Puerto Rico, with the public corporation responsible for administering a health insurance system that provides medical and hospital care to indigent residents. The complaint also charged that to achieve their goals, members of the College called for an eight-day strike during which they ceased providing non-emergency services to patients. The order prohibits the defendants from boycotting or refusing to deal with any third-party payer, refusing to provide medical services to patients of any third-party payer, or jointly negotiating prices or other more favorable economic terms. The order also calls for the College to pay \$300,000 to the catastrophic fund administered by the Puerto Rico Department of Health. The order does not prevent the defendants from participating in joint ventures that involve financial risk-sharing or which receive the prior approval of the Commission, from petitioning the government, or from communicating purely factual information about health plans.
- 20. Montana Associated Physicians, Inc./Billing Physician Hospital Alliance, Inc., 123 F.T.C. 62 (1997) (consent order). The complaint charged that a physician association (MAPI) blocked the entry of an HMO into Billings, Montana, obstructed a PPO that was seeking to enter, recommended physician fee increases, and later acted through a physician-hospital organization (BPHA) to maintain fee levels. The order prohibits MAPI and BPHA from agreeing, for a 20 year period, to 1) boycott or refuse to deal with third-party payers; 2) determining the terms upon which physicians deal with such payers; and 3) fixing the fees charged for any physician services. MAPI also is prohibited from advising physicians to raise,

maintain, or adjust the fees charged for their medical services, or creating or encouraging adherence to any fee schedule. The order does not prevent these associations from entering into legitimate joint ventures that are non-exclusive and involve the sharing of substantial financial risk. Other types of joint ventures are subject to prior approval of the Commission.

- 21. **RxCare of Tennessee, Inc. et al.**, 121 F.T.C. 762 (1996) (consent order). The complaint charged that RxCare of Tennessee, a leading provider of pharmacy network services in that state, used a "most favored nation" clause (MFN) in order to discourage pharmacies from discounting, and to limit price competition among pharmacies in their dealings with pharmacy benefits managers and third-party payers. The MFN clause at issue required that if a pharmacy in the RxCare network accepted a reimbursement rate from any other third-party payer that is lower than the RxCare rate, the pharmacy must accept that lower rate for all RxCare business in which it participates. Combined with RxCare's market power (the network included 95% of all chain and independent pharmacies in Tennessee), the complaint alleged that the MFN clause forced some pharmacies in the network to reject lower reimbursement rates for prescriptions they fill for patients covered by other health plans. The order bars RxCare from including the MFN clause in its pharmacy agreements.
- 22. La Asociacion Medica de Puerto Rico, 119 F.T.C. 772 (1995) (consent order). The complaint charged that the Medical Association of Puerto Rico, its Physiatry Section, and two of its physiatrist members illegally conspired to boycott a government insurance program in order to obtain exclusive referral powers from insurers and to increase reimbursement rates. The order prohibits the respondents from agreeing to boycott or refuse to deal with any third-party payer, or refusing to provide services to patients covered by any third-party payer. For a five-year period, the order also: 1) places restrictions on meetings of physiatrists to discuss refusals to deal with any third-party payer, or the provision of services covered by any third-party payer; and 2) prohibits the respondents from soliciting information from physiatrists about their decisions to participate in agreements with insurers and provide service to patients, passing such information along to other doctors, and giving physiatrists advice about making those decisions.
- 23. Trauma Associates of North Broward, Inc., 118 F.T.C. 1130 (1994) (consent order). The complaint charged that ten surgeons in Broward County, Florida, through Trauma Associates of North Broward, Inc., conspired to fix the fees they were paid for their services at trauma centers at two area hospitals, and threatened and carried out a concerted refusal to deal, forcing one trauma center to close. Under the consent order, the surgeons agreed to dissolve Trauma Associates of North Broward, Inc., a corporation which allegedly served as a vehicle for the surgeons to engage in collective negotiations with the North Broward Hospital District on fees and other contract terms. The order also prohibited the surgeons from dealing with any

provider of health care services on collectively-determined terms unless the surgeons are partners or employees in a corporation, or are acting through an "integrated" joint venture and remain free to deal individually with entities that decline to deal with the joint venture.

- 24. McLean County Chiropractic Association, 117 F.T.C. 396 (1994) (consent order). The complaint charged that an association of chiropractors set maximum fees for its members and attempted to negotiate collectively on behalf of those members the terms and conditions of agreements with third-party payers. The order prohibits the respondents from agreeing to determine their fees collectively or dealing with payers on collectively determined terms.
- 25. Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists **Association**, 117 F.T.C. 95 (1994) (consent order). The complaint alleged that the Maryland Pharmacists Association (MPhA) and the Baltimore Metropolitan Pharmaceutical Association (BMPA), in response to cost-containment measures initiated by the Baltimore city government employees' prescription-drug plan, illegally conspired to boycott the plan in order to force higher reimbursement rates for prescriptions. According to the complaint, the associations' actions increased the cost of obtaining drugs through prescription drug plans, and reduced price competition between the firms providing these prescriptions. Under the consent order, MPhA and BMPA are prohibited from entering into, organizing, or encouraging any agreement between or among pharmacy firms to refuse to enter into, or to withdraw from, any participation agreement offered by a third-party payer. In addition, for five years, the associations are prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, or the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement. The associations are also prohibited from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement.
- Southeast Colorado Pharmacal Association, 116 F.T.C. 51 (1993) (consent order). The complaint alleged that the Southeast Colorado Pharmacal Association (SCPhA) illegally conspired to boycott a prescription drug program offered through a state-retirees health plan in an attempt to force the program to increase its reimbursement rate for prescriptions filled by its pharmacy members. The order prohibits the association from entering into or threatening to enter into any agreement with pharmacies to withdraw or refuse to participate in similar reimbursement programs in the future. In addition, for five years, SCPhA is prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, communicating the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement, or soliciting other pharmacy firms' intentions about entering into a participation agreement. The association is also prohibited from continuing meetings of pharmacy representatives if members make statements

concerning their firms' intentions to join a participation agreement.

- 27. **Roberto Fojo, M.D.**, 115 F.T.C. 336 (1992) (consent order). The complaint charged that the former chairman of the ob/gyn department at a hospital in Miami, Florida, along with other department members, coerced the hospital into paying ob/gyns and other physicians for emergency room call services by threatening to refuse to take emergency room call duty. The order prohibits Dr. Fojo from conspiring with other physicians to boycott or threaten to boycott the emergency room at any hospital.
- 28. <u>Debes Corporation</u>, 115 F.T.C. 701 (1992) (consent order). The complaint charged that six nursing homes in the Rockford, Illinois area stopped using temporary nurse registries, following an increase in prices charged by the registries for nursing assistants, in order to eliminate competition among the nursing homes for the purchase of nursing services provided by the registries. The order prohibits the nursing homes from agreeing to boycott the registries, which supplied temporary nursing services to the nursing homes, or to interfere with prices charged by such registries.
- 29. Southbank IPA, Inc., 114 F.T.C. 783 (1991) (consent order). The complaint charged that twenty three obstetrician/gynecologists in Jacksonville, Florida, illegally conspired to fix the fees they charged to third-party payers, boycotted or threatened to boycott third-party payers, and restrained competition among ob/gyns in the Jacksonville, Florida area. Under the order, the physicians agreed: 1) to dissolve their independent practice association and its parent corporation; 2) not to enter into or attempt to enter into any agreement or understanding with any competing physician to fix, stabilize, or tamper with any fee, price, or any other aspect of the fees charged for any physician's services; and 3) not to deal with any third-party payer on collectively-determined terms unless they are participating in an "integrated" joint venture as defined by the order, or in a partnership or professional corporation. The consent agreement marked the first time dissolution of a health care organization was required as a term of settlement.
- 30. Chain Pharmacy Association of New York State, Inc., 114 F.T.C. 327 (1991) (consent order). The complaint charged that the Chain Pharmacy Association (Chain) and its members conspired to boycott the New York State Employees Prescription Plan, in order to force an increase in reimbursement rates for plan participants who provide prescriptions to state employees. The complaint alleged that the collective refusal to participate in the program injured consumers in New York by reducing competition among pharmacy firms with respect to third-party prescription plans. The order prohibits Chain from organizing or entering into any agreement among pharmacy firms to withdraw from or refuse to enter into third-party payer prescription drug plans. Also, for a period of ten years, the order prohibits Chain from

communicating to any pharmacist or pharmacy firm information regarding any other pharmacy firm's intentions to enter or refuse to enter into such a participation agreement, or from continuing meetings of pharmacy firm representatives if two persons make statements concerning their firms' intentions to join a participation agreement. For a period of eight years, the order prohibits Chain from advising another pharmacy firm on whether to enter into any payer participation agreement. See Pharmaceutical Society of the State of New York, Inc. (discussed below).

- 31. Peterson Drug Company of North Chili, New York, Inc., 115 F.T.C. 492 (1992) (consent order). As a member firm of Chain Pharmacy Association, Peterson Drug Company of North Chili, New York, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 32. **Fay's Drug Company, Inc.**, 114 F.T.C. 171 (1991) (consent order). As a member firm of Chain Pharmacy Association, Fay's Drug Company, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 33. **Kinney Drugs, Inc.**, 114 F.T.C. 367 (1991) (consent order). As a member firm of Chain Pharmacy Association, Kinney Drugs, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 34. <u>Melville Corporation</u>, 114 F.T.C. 171 (1991) (consent order). As a member firm of Chain Pharmacy Association, Melville Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 35. **Rite Aid Corporation**, 114 F.T.C. 182 (1991) (consent order). As a member firm of Chain Pharmacy Association, Rite Aid Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 36. **James E. Krahulec**, 114 F.T.C. 372 (1991) (consent order). As a member firm of Chain Pharmacy Association, James E. Krahulec, along with Rite Aid and the members of Chain Pharmacy Association, was charged with conspiracy to restrain trade in its refusal to participate

in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

- Pharmaceutical Society of the State of New York, Inc., 113 F.T.C. 661 (1990) (consent 37. order). The complaint charged that the Pharmaceutical Society of the State of New York, Inc. (PSSNY) conspired to boycott the New York State Employees Prescription Plan, in order to force an increase in reimbursement rates for plan participants who provide prescription drugs to state employees. According to the complaint, the society's actions reduced price competition, forced the state to pay substantial additional sums for prescription drugs, and coerced the state into raising the prices paid to pharmacies under the state plan. Under the consent order, the society agreed not to enter into any agreement between pharmacy firms to withdraw from or refuse to enter into any participation agreement. Also, for a period of ten years, the order prohibits PSSNY from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement; and requires PSSNY to refrain from communicating to any pharmacist or pharmacy firm any information regarding any other pharmacy firm's intentions to enter or refuse to enter into such a participation agreement. For a period of eight years, the order prohibits PSSNY from providing comments or advice to any pharmacist or pharmacy on the desirability of participating in any existing or proposed participation agreement. See Chain Pharmacy Association (discussed above).
- 38. <u>Empire State Pharmaceutical Society, Inc.</u>, 114 F.T.C. 152 (1991) (consent order). An affiliate of Long Island Pharmaceutical Society, Empire State Pharmaceutical Society was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.
- 39. <u>Capital Area Pharmaceutical Society</u>, 114 F.T.C. 159 (1991) (consent order). An affiliate of PSSNY, Capital Area Pharmaceutical Society was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.
- 40. Alan Kadish, 114 F.T.C. 167 (1991) (consent order). As president of PSSNY, Alan Kadish was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.
- 41. <u>Long Island Pharmaceutical Society, Inc.</u>, 113 F.T.C. 669 (1990) (consent order). An affiliate of PSSNY, Long Island Pharmaceutical Society, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate

order similar to the PSSNY order (discussed above) was entered.

- 42. **Pharmaceutical Society of Orange County, Inc.**, 113 F.T.C. 645 (1990) (consent order). An affiliate of PSSNY, Pharmaceutical Society of Orange County, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.
- 43. Westchester County Pharmaceutical Society, Inc., 113 F.T.C. 159 (1990) (consent order). An affiliate of PSSNY, Westchester County Pharmaceutical Society, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.
- 44. **Brooks Drug, Inc.**, 112 F.T.C. 28 (1989) (consent order). As a member firm of Chain Pharmacy Association, Brooks Drug Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 45. <u>Carl's Drug Co., Inc.</u>, 112 F.T.C. 15 (1989) (consent order). As a member firm of Chain Pharmacy Association, Carl's Drug Co., Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 46. <u>Genovese Drug Stores, Inc.</u>, 112 F.T.C. 23 (1989) (consent order). As a member firm of Chain Pharmacy Association, Genovese Drug Stores, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.
- 47. **Preferred Physicians, Inc.**, 110 F.T.C. 157 (1988) (consent order). The complaint charged that two hundred and fifty physicians in Tulsa, Oklahoma, effectively controlled patient access to the leading hospital in the area, and formed a stock corporation to conduct joint negotiations with third-party payers on the members' behalf. According to the complaint, the corporation had been formed as an exclusive negotiating agent of the otherwise competing members for the purpose of resisting pressure to provide discounts to HMOs and other third-party payers who might seek contracts with members of the corporation. Under the consent order, the corporation agreed not to enter into agreements with its members to deal with third-party payers on collectively determined terms, not to communicate to third-party payers that its members would not participate in plans on terms unacceptable to the corporation, and for five

years not to advise its members on the desirability of prices paid for physicians' services by third-party payers.

- 48. Rochester Anesthesiologists, et al., 110 F.T.C. 175 (1988) (consent order). The complaint charged that thirty-one anesthesiologists in Rochester, New York conspired to increase their fees by negotiating collectively with third-party payers over reimbursement terms, and by threatening not to participate in certain health plans. The complaint further alleged that the anesthesiologists jointly departicipated from Blue Shield when it refused to accede to their demand for higher reimbursement rates. The order prohibits the anesthesiologists from agreeing to conspire to deal with third-party payers on collectively determined terms or to coerce third-party payers.
- 49. New York State Chiropractic Association, 111 F.T.C. 331 (1988) (consent order). The complaint charged that a chiropractic association conspired with its members to increase the level of reimbursement paid for chiropractic services by collectively threatening not to participate, and by departicipating from a program of a third-party payer. The order prohibits the association from agreeing to conspire to deal with third-party payers on collectively determined terms, act on behalf of its members to negotiate with third-party payers, or coerce third-party payers.
- 50. Patrick S. O'Halloran, M.D. (Formerly Newport Rhode Island Obstetricians) 111 F.T.C. 35 (1988) (consent order). The complaint charged that five obstetricians in the Newport, Rhode Island area concertedly forced the state to raise Medicaid payments to obstetricians by threatening to refuse to accept new Medicaid patients if the state did not raise Medicaid payments. The order prohibits the physicians from agreeing to conspire to deal with any governmental health care program on collectively determined terms, or to coerce any governmental health care program.
- Oklahoma Optometric Association, 106 F.T.C. 556 (1985) (consent order). The complaint charged that a state optometric association, through its ethical guidelines, unreasonably restricted its members from truthful advertising and soliciting business. By virtue of these guidelines, members were prohibited from, among other things, associating with lay practices, making superiority claims, offering specific guarantees (e.g., to refund the cost of optical goods), and criticizing other optometrists. Under the order, the association agreed to cease restricting its members from truthful advertising and soliciting business, from meeting competitors' prices, and from offering special guarantees, such as refunds to consumers for the cost of optical goods.

- 52. Michigan State Medical Society, 101 F.T.C. 191 (1983). The complaint charged that an East Lansing, Michigan medical society illegally obstructed insurers' cost containment programs, by orchestrating a group boycott by its physician members for the purpose of obtaining higher reimbursement. According to the complaint, the medical society organized a proxy campaign which would have allowed the society to collectively terminate its members' participation in third-party payer and Medicaid insurance programs. The Commission decision held that the medical society illegally conspired to obtain its members' permission to collectively terminate participation in third-party payer and Medicaid insurance programs if these payers did not alter cost containment procedures and adopt reimbursement policies acceptable to the society. The order prohibited the medical society from, among other things, entering into agreements with its members to affect the amount, terms of reimbursement, or decision to accept or reject an agreement; acting on behalf of its members through proxy power; influencing its members to refuse to enter into any participation agreement not acceptable to the society; and entering into any agreement with third party payers concerning the amount, manner of calculation, or terms of reimbursement.
- 53. Association of Independent Dentists, 100 F.T.C. 518 (1982) (consent order). The complaint charged that an association of dentists in Pueblo County, Colorado, illegally restrained competition among its members by adopting and enforcing a bylaw that prevented or hindered its members from truthfully advertising any aspect of their practices without the prior approval of the association's Board of Directors. According to the complaint the association threatened to refuse to sign participating dentist agreements with third-party payers, in order to pressure these payers to increase or maintain the level of reimbursement paid for dental services. Under the order, the medical society agreed to cease restricting truthful advertising by its members, and not to act in any way to coerce third-party payers to accept its positions about reimbursement in dental care coverage plans.
- 54. American Medical Association, 94 F.T.C. 701 (1979), aff'd as modified, 638 F.2D 443 (2d Cir. 1980), aff'd by an equally divided Court, 455 U.S. 676 (1982) (order modified 99 F.T.C. 440 (1982), 100 F.T.C. 572 (1982) and 114 F.T.C. 575 (1991)). The complaint charged the AMA with violations of Section 5 of the FTC Act by agreeing to restrict its members' ability to advertise and solicit patients, and engage in price competition and other competitive practices. The Commission decision held that the AMA had illegally engaged in concerted action to restrain competition among its members. The Commission found, among other things, that the AMA, through its ethical guidelines, unreasonably prevented or hindered its members from soliciting business by truthful advertising or other forms of solicitation of patients. In addition the Commission found that the AMA had illegally restrained its members from offering services on a salaried basis or at below-usual rates for hospitals, HMOs, and other lay institutions. Under the order, the association is prohibited from restraining truthful advertising. The order also prohibits the AMA from placing restrictions on the operation of

physician practices that limit a patient's choice of physician services.

- 55. California Medical Association, 93 F.T.C. 519 (1979) (consent order) (modified 105 F.T.C. 277 (1985)) (set aside order, 120 F.T.C. 858 (1995)). The complaint charged that a medical association's preparation, publication, and circulation of RVSs, which included instructions for the computation and use of conversion factors, had the effect of establishing, maintaining, or otherwise influencing the fees which physicians charged for their services. The order prohibits the respondent from developing, publishing, or circulating RVSs, or suggesting that monetary conversion factors be applied to RVSs.
- Minnesota Medical Association, 90 F.T.C. 337 (1977) (consent order). The complaint charged that a medical association's preparation, publication, and circulation of RVSs had the effect of establishing, maintaining, or otherwise influencing the fees which physicians charged for their services. The complaint also charged that the association's component societies had adopted, published, circulated, and recommended to their members conversion factors applicable to the RVSs. The order prohibits the association from developing, publishing, or circulating RVSs and monetary conversion factors applicable to RVSs.
- 57. American College of Radiology, 89 F.T.C. 144 (1977) (consent order) (modified 113 F.T.C. 280 (1990)). The complaint charged that a medical association's preparation, publication, and circulation of RVSs had the effect of establishing, maintaining, or otherwise influencing the fees which physicians charged for their services. The order prohibits the association from developing, publishing, or circulating RVSs.
- 58. American Academy of Orthopaedic Surgeons, 88 F.T.C. 968 (1976) (consent order) (modified 105 F.T.C. 248 (1985)) (set aside order, 119 F.T.C. 609 (1995)). The complaint charged that a medical association's preparation, publication, and circulation of RVSs had the effect of establishing, maintaining, or otherwise influencing the fees which physicians charged for their services. The order prohibits the association from developing, publishing, or circulating RVSs.
- 59. <u>American College of Obstetricians & Gynecologists</u>, 88 F.T.C. 955 (1976) (consent order) (modified 104 F.T.C. 524 (1984)). The complaint charged that a medical association's preparation, publication, and circulation of RVSs had the effect of establishing, maintaining, or otherwise influencing the fees which physicians charged for their services. The order prohibits the association from developing, publishing, or circulating RVSs.

- D. Agreements to Obstruct Innovative Forms of Health Care Delivery or Financing
- 1. Asociacion de Farmacias Region de Arecibo (See Section II B for citation and annotation.)
- 2. **Ernesto L. Ramirez Torres, D.M.D., et al.** (See Section II B for citation and annotation.)
- 3. <u>M.D. Physicians of Southwest Louisiana Inc.</u> (See Section II B for citation and annotation.)
- 4. <u>Montana Associated Physicians, Inc./Billings Physicians Hospital Alliance, Inc.</u> (See Section II B for citation and annotation.)
- 5. <u>La Asociacion Medica de Puerto Rico</u> (See Section II B for citation and annotation.)
- 6. Medical Staff of Good Samaritan Regional Medical Center, 119 F.T.C. 106 (1995) (consent order). The complaint charged that members of the medical staff of Good Samaritan Regional Medical Center, in Phoenix, Arizona, consisting of more than 500 physicians, conspired to prevent the hospital from opening a multi-specialty clinic that would have competed with the physicians, by threatening to stop admitting patients to the hospital if it proceeded with plans to open the clinic. The order prohibits members of the medical staff from agreeing, or attempting to enter into an agreement, to prevent or restrict the services offered by Good Samaritan, the clinic, or any other health care provider. The order also prohibits the physicians from conspiring to use coercive tactics to prevent competition from other physicians or health care providers.
- Physician Group, Inc., 120 F.T.C. 567 (1995) (consent order). The complaint charged that Physicians Group Inc., and seven physicians on the board of directors of that organization, conspired to prevent or delay the entry of third-party payers into Pittsylvania County and Danville, Virginia. The complaint also charged that the respondents fixed the terms on which they would deal with third-party payers, including not only price terms but also terms and conditions of cost containment. The order prohibits such conduct, and requires the dissolution of Physicians Group Inc.
- 8. **Southbank IPA, Inc.** (See Section II B for citation and annotation.)

- 9. **Diran Seropian, M.D.**, 115 F.T.C. 891 (1992) (consent order). Dr. Seropian was charged along with physicians and other health practitioners in Medical Staff of Broward General Medical Center (discussed below). He entered a separate consent agreement after litigation against him had commenced.
- Medical Staff of Holy Cross Hospital, 114 F.T.C. 555 (1991) (consent order). The 10. complaint charged that physicians and other health practitioners with privileges to practice at a Fort Lauderdale, Florida hospital conspired with its members to threaten to boycott the hospital, in order to coerce the hospital not to enter a business relationship with the Cleveland Clinic or grant privileges to Clinic physicians. The medical staff entered into a consent order under which it will not, among other things, 1) refuse to deal or threaten to refuse to deal with the hospital or any other provider of health care services; 2) refuse or threaten to refuse to provide, or delay unreasonably in providing, an application for medical staff privileges to any Cleveland Clinic physician; 3) deny, impede, or refuse to consider any application for hospital changes or for changes in hospital privileges by any person solely because of his or her affiliation with the Cleveland Clinic; and 4) (i) deny or recommend to deny, limit, or otherwise restrict hospital privileges for any Cleveland Clinic physician, or (ii) close or recommend to close the medical staff, without a reasonable basis for concluding that the denial, limitation, or restriction serves the interests of the hospital in providing for the efficient and competent delivery of health care services.
- 11. Medical Staff of Broward General Medical Center, 114 F.T.C. 542 (1991) (consent order). The complaint charged that the medical staff of physicians and other health practitioners with privileges to practice at a Fort Lauderdale, Florida hospital conspired with its members to threaten to boycott the hospital, in order to coerce the hospital not to enter a business relationship with the Cleveland Clinic or grant privileges to Clinic physicians. The medical staff entered into a consent order under which it will not, among other things, 1) refuse to deal or threaten to refuse to deal with the hospital or any other provider of health care services; 2) deny, impede, or refuse to consider any application for hospital changes or for changes in hospital privileges by any person solely because of his or her affiliation with the Cleveland Clinic; and 3) deny or recommend to deny, limit, or otherwise restrict hospital privileges for any Cleveland Clinic physician without a reasonable basis for concluding that the denial, limitation, or restriction serves the interests of the hospital in providing for the efficient and competent delivery of health care services.
- 12. <u>Medical Staff of Dickinson County Memorial Hospital</u>, 112 F.T.C. 33 (1989) (consent order). The complaint charged that twelve physicians practicing in Dickinson County, Michigan, two medical societies, and a hospital medical staff conspired to prevent a hospital from opening a clinic that would have competed with the doctors, by threatening not to refer

patients to specialists at the hospital. The order prohibits the respondents from conspiring to use coercive tactics to prevent competition from other physicians or health care providers. The order provides that legitimate peer review activities are not prohibited.

- 13. <u>Lee M. Mabee, M.D.</u>, 112 F.T.C. 517 (1989) (consent order). Dr. Mabee was charged along with 11 other obstetricians in Certain Sioux Falls Obstetricians (discussed below). He entered a separate consent agreement after the litigation against him had commenced.
- 14. <u>Eugene M. Addison, M.D.</u> (formerly Huntsville Physicians) 111 F.T.C. 339 (1988) (consent order). The complaint charged that fourteen physicians in the Huntsville, Texas area collectively sought to obtain from HMOs more advantageous terms of participation and, when those efforts proved unsuccessful, collectively refused to deal with the HMOs and attempted to restrict the hospital privileges of physicians associated with the HMOs. Under the order, the physicians agreed not to deal collectively with HMOs or health plans, not to deny hospital staff privileges solely because the applicant was associated with an HMO or health plan, and not to change the hospital's rules or medical staff bylaws in order to limit the participation of any physician in governance of the hospital or medical staff because of affiliation with an HMO or health plan.
- 15. **Iowa Chapter of American Physical Therapy Association**, 111 F.T.C. 199 (1988) (consent order). The complaint charged that a physical therapy association unreasonably restrained competition by adopting a resolution declaring it illegal and unethical for therapists to work for physicians. The order prohibits the association from restricting member therapists from being employed by physicians.
- 16. New York State Chiropractic Association (See Section II B for citation and annotation.)
- 17. **Rochester Anesthesiologists et al.** (See Section II B for citation and annotation.)
- 18. Medical Staff of Doctors' Hospital of Prince George's County, 110 F.T.C. 476 (1988) (consent order). The complaint charged that the medical staff of a Maryland hospital conspired to coerce the owner of the hospital to abandon plans to open an HMO facility in the area, through threats of concerted action to "close" the hospital. Under the order, the medical staff agreed not to organize or encourage any agreement among physicians for the purpose of preventing delivery of health care services by HMOs or other health care facilities.
- 19. <u>Medical Staff of Memorial Medical Center</u>, 110 F.T.C. 541 (1988) (consent order). The complaint charged that the medical staff of a hospital in Savanna, Georgia, acting through its

credentials committee, conspired to suppress competition by denying a certified nurse-midwife's application for hospital privileges without a reasonable basis. The order prohibits the medical staff from agreeing to deny or restrict hospital privileges to certified nurse-midwives, unless the staff has a reasonable basis for believing that the restriction would serve the interest of the hospital in providing for the efficient and competent delivery of health care services.

- 20. **Robert E. Harvey, M.D.**, 111 F.T.C. 57 (1988) (consent order). The complaint charged that allergists and a clinic in the Victoria, Texas area organized a boycott of manufacturers of new allergy testing products which were being marketed to non-allergist physicians. The order prohibits the allergists from agreeing to conspire to use coercive tactics to prevent competition from doctors who were not allergists.
- 21. <u>Certain Sioux Falls Obstetricians</u>, 111 F.T.C. 122 (1988) (consent order). The complaint charged that eleven obstetricians in the Sioux Falls, South Dakota area, who served as the part-time OB faculty of the medical school, illegally attempted to limit competition from the medical school full-time faculty members by threatening a boycott of the obstetrician/gynecologist residency program. The order prohibits the physicians from agreeing to engage in collective coercive activities that interfere with the residency program of the University of South Dakota School of Medicine.
- States District Court, Nurse Midwifery Associates v. Hibbett, 918 F.2d 605 (6th Cir. 1990), appealing 689 F. Supp. 799 (M.D. Tenn. 1988). In an antitrust case by two self-employed nurse midwives against a physician-owned malpractice insurance company, which had canceled the malpractice insurance of an obstetrician who had agreed to collaborate with the nurse midwives, the Commission filed an amicus brief arguing that the District Court erred in holding that the physician-controlled corporation must be viewed as a single entity and that its conduct therefore could not be deemed to be concerted action cognizable under the antitrust laws. The Sixth Circuit reversed the District Court on this issue.
- 23. **Preferred Physicians, Inc.** (See Section II B for citation and annotation.)
- 24. **Physicians of Meadville**, 109 F.T.C. 61 (1987) (consent order). The complaint charged that sixty-one physicians combined to restrict competition among physicians, by threatening not to refer patients to physician specialists practicing on the medical staff of a hospital in Erie, Pennsylvania, if a group of specialists associated with that hospital opened a satellite office that would compete with the local doctors. The order prohibits the physicians from agreeing to concertedly withhold or threaten to withhold patient referrals from any physician or other health

care provider, or to refuse to deal with or withhold patient admissions from any hospital.

- 25. American Academy of Optometry, 108 F.T.C. 25 (1986) (consent order). The complaint charged that an Academy of optometrists engaged in unlawful concerted action to restrain competition among its members by adopting and enforcing ethical guidelines that unreasonably prevented or hindered its members from soliciting business through truthful advertising and similar means. By virtue of these guidelines, members had been restricted from advertising prices, fees, types of treatment, professional training and experience, special expertise, and products offered for sale, such as contact lenses. The order prohibits the Academy from restricting its members from truthfully advertising and soliciting business. Under the order, the association also agreed to cease restricting its members in their choice of office location.
- 26. Health Care Management Corp., 107 F.T.C. 285 (1986) (consent order) (formerly Medical Staff of North Mobile Community Hospital). The complaint charged that a corporation that owns a hospital near Mobile, Alabama, and the hospital's medical staff conspired to restrain competition from podiatrists, by pressuring individual physicians not to coadmit the patients of a podiatrist already on the staff, and by imposing unreasonable conditions on podiatrists seeking to practice at the hospital. The hospital and its medical staff agreed not to unreasonably restrict podiatrists from practicing at the hospital.
- 27. North Carolina Orthopaedic Association, 108 F.T.C. 116 (1986) (consent order). The agreement settled complaint charges that an orthopaedic association orchestrated an agreement among its members to exclude or unreasonably discriminate against podiatrists who sought hospital privileges or access to hospitals. The order prohibits the association from unreasonably restricting podiatrists from gaining surgical privileges or access to hospitals in North Carolina.
- 28. Hawaii Dental Service Corp., 106 F.T.C. 25 (1985) (consent order). The complaint charged that a corporation that offered a dental insurance plan, which provided dental services for a prepaid premium and was operated by the dentists who provided the services, limited competition among dentists in the state by enacting bylaws that prohibited the corporation from recruiting and sending dentists to certain counties without the approval of the majority of its members residing in the affected counties. The order prohibits the corporation from conditioning its decisions to send new dentists to certain counties in Hawaii on the approval of member dentists already practicing in those counties.
- 29. <u>Medical Staff of John C. Lincoln Hospital & Health Center</u>, 106 F.T.C. 291 (1985) (consent order). The complaint charged that physicians and other practitioners with privileges to practice at a Phoenix, Arizona hospital and health center conspired to coerce and threaten to

boycott the hospital, so that the hospital would cancel its involvement with an urgent care facility that competed with medical staff members. The order prohibits the medical staff from agreeing to make, or join in plans to make, any threats of unreasonably discriminatory action against any health care facility or professional, or to undertake coercive action to influence reimbursement or insurance determinations, including a refusal to refer, admit, or treat patients.

- 30. Michigan Optometric Association, 106 F.T.C. 342 (1985) (consent order). The complaint charged that an optometric association conspired with its members to place unreasonable restraints upon member optometrists' "corporate practices." According to the complaint the optometric association engaged in illegal concerted action to restrain competition among its members by adopting and enforcing ethical guidelines that unreasonably prevented or hindered its members from truthfully advertising. The ethical guidelines had prohibited members from displaying their names in any manner that stood out from a listing of other occupants of a building; from using professional cards, billboards, letterheads, or stationery containing any information other than certain limited items; from using large signs or any representations of eyes, eyeglasses, or the human head; and from using lettering that was larger than a specified size on windows or doors. The order prohibits the association from restricting its members from truthfully advertising and otherwise soliciting business, providing services or selling optical goods in a retail location, or from providing optometric services or optical goods through corporate practice (i.e., in association with any business corporations other than hospital clinics, HMOs, or professional corporations).
- 31. State Volunteer Mutual Insurance Corp., 102 F.T.C. 1232 (1983) (consent order). The complaint charged that a Tennessee physician-owned insurance company providing malpractice insurance terminated the insurance of a physician because he had agreed to serve as a back-up physician to certified nurse-midwives who were in independent practice. The order prohibits the insurance company from unreasonably discriminating against physicians who work with independent nurse midwives.
- 32. <u>Indiana Federation of Dentists</u>, 101 F.T.C. 57 (1983), rev'd, 745 F.2d 1124 (7th Cir. 1984), rev'd, 476 U.S. 447 (1986). The complaint charged that an organization conspired to restrain competition among Indiana dentists by promulgating guidelines to prevent dentists from turning over patients' x-rays to dental care insurers. The Supreme Court reversed the Seventh Circuit and affirmed the Commission's holding that the organization of dentists illegally conspired to obstruct third-party payers' cost containment programs through the concerted withholding of patients' x-rays. The order prohibits the dental association from agreeing to obstruct third-party payers use of x-rays or other materials for dental benefit determinations, from compelling a third-party payer to deal with dental health care plans in a certain manner, or influencing a patient's choice of dentists based on the dentist's degree of cooperation with the

third-party payer.

- 33. <u>Michigan State Medical Society</u>, (See Section II B for citation and annotation.)
- 34. **Texas Dental Association**, 100 F.T.C. 536 (1982) (consent order). The complaint charged that a state dental association orchestrated member dentists' withholding of x-rays from insurers who needed them to make benefit determinations. The order prohibits the association from obstructing third-party payers from the predetermination and limitation of dental coverage to the least expensive form of treatment, and from coercing payers to modify dental care coverage plans.
- 35. Sherman A. Hope, M.D., 98 F.T.C. 58 (1981) (consent order). The complaint charged that five physicians discontinued emergency room coverage to force a Texas hospital to halt its plans to recruit a new physician under financial terms that the physicians opposed. The order prohibits the physicians from undertaking any course of conduct to interfere with the hospital's recruitment of physicians or the hospital's efforts to grant hospital privileges to physicians.
- 36. American Medical Association, (See Section II B for citation and annotation.)
- 37. **Forbes Health System Medical Staff**, 94 F.T.C. 1042 (1979) (consent order). The complaint charged that the medical staff of a Pennsylvania hospital system, consisting of physicians, dentists, and podiatrists, which was starting its own HMO, had abused the hospital privilege system to hamper competition from a competing HMO. In particular, the group allegedly denied applications by the HMO-affiliated physicians. The order prohibits the group from discriminating against medical staff members who were associated with HMOs, and from excluding applicants for hospital privileges simply because they provided services on other than a fee-for-service basis.
- 38. <u>Indiana Dental Association</u>, 93 F.T.C. 392 (1979) (consent order). The complaint charged that a state dental association restrained competition among dentists by engaging in concerted action to withhold x-rays from insurers who needed them to make benefit determinations. The order prohibits the dental association from obstructing third-party payers from predetermination of benefits and limitation of dental coverage to the least expensive course of treatment.
- 39. <u>American Society of Anesthesiologists</u>, 93 F.T.C. 101 (1979) (consent order). The complaint charged that a medical society, through its ethical guidelines and membership requirements, restrained member anesthesiologists from being paid on other than a fee-for-

service basis or from becoming salaried employees at hospitals. The order prohibits the association from restricting its members from rendering services other than on a fee-for-service basis.

40. Medical Service Corp. of Spokane County, 88 F.T.C. 906 (1976) (consent order). The complaint charged that a Blue Shield health payment plan and an affiliated physicians' association in the state of Washington deterred the development of HMOs by denying reimbursement to physicians who provided services to HMOs. The order prohibits the plan and association from pursuing any course of conduct that discriminates against HMOs, or against any physician who practices medicine with an HMO or in any manner other than on a fee-for-service basis.

E. Restraints on Advertising and Other Forms of Solicitation

1. Private Association Restraints

- 1. <u>Colegio de Cirujanos Dentistas de Puerto Rico</u>, (See Section II B for citation and annotation.)
- 2. California Dental Association, 121 F.T.C. 190 (1996) (final order), aff'd 128 F.3d 720 (9th Cir. 1997); vacated, remanded 526 U.S. 756 (1999); rev'd, remanded 224 F.3d 942 (9th Cir. 2000); Order Returning Matter to Adjudication and Dismissing Complaint (FTC Commission Actions: February 15, 2001 (www.ftc.gov)). The Commission's opinion affirmed an ALJ's decision finding that the California Dental Association violated Section 5 of the FTC Act by unreasonably restricting truthful, nondeceptive advertising. The Commission found that CDA's restrictions on price advertising were per se illegal, and analyzed CDA's non-price advertising restraints under an abbreviated rule of reason. On 10/22/97, the Ninth Circuit affirmed the Commission's order in a 2-1 decision, holding that the Commission has jurisdiction over CDA, and that the agreement unreasonably restrained trade under a "quick look" rule of reason analysis. The appeals court found a per se analysis inappropriate for the price advertising restrictions. The Supreme Court granted CDA's petition for certiorari and on 5/24/99 vacated and remanded the Ninth Circuit opinion. The Court upheld the appeals court's decision regarding the Commission's jurisdiction over non-profit entities that engage in activities for the economic benefit of their members, but remanded the case to the Ninth Circuit for a fuller consideration of the rule of reason analysis. The Ninth Circuit held that the FTC had failed to prove that CDA's advertising restrictions were anticompetitive under a rule of reason analysis, and then vacated and remanded the judgment of the FTC on September 5, 2000, and instructed the FTC to dismiss its case against CDA. The Ninth Circuit denied a Commission

petition for rehearing *en banc* on November 17, 2000. The Commission issued an order on February 15, 2001 dismissing the case. In a separate statement, Commissioners Pitofsky, Anthony and Thompson stated that although they had concerns about some aspects of the Ninth Circuit's final ruling, other considerations such as CDA's compliance with the 1996 order and the outdated nature of the factual record, made seeking review at the Supreme Court impractical.

- 3. National Association of Social Workers, 116 F.T.C. 140 (1993) (consent order). The complaint charged that a professional association of social workers engaged in unlawful concerted action by adopting rules to restrain competition among social workers, by prohibiting association members from 1) using testimonials and other forms of truthful advertising; 2) soliciting the clients of other social workers, even where the clients are not vulnerable to abusive solicitation practices; and 3) prohibiting social workers from paying a fee for receiving a referral. The order prohibits the association from restricting its members from truthful advertising or solicitation, or participation in patient referral services. The order allows the association to adopt reasonable rules to restrict false or deceptive advertising, regulate solicitation of business or testimonials from persons vulnerable to undue influence, and ban solicitation of testimonials from current psychotherapy patients. The association is also permitted to require disclosure of fees that social workers pay to patient referral services.
- 4. <u>American Psychological Association</u>, 115 F.T.C. 993 (1992) (consent order). The complaint charged that a professional association of psychologists engaged in unlawful concerted action by adopting and enforcing rules to restrain competition among psychologists by prohibiting association members from 1) truthfully advertising comparative statements on services, testimonials, or direct solicitation; and 2) banning participation in certain patient referral services. The order prohibits the association from restricting its members from truthful advertising, solicitation, or participation in patient-referral services. Under the order, the association may adopt reasonable rules to restrict false or deceptive advertising, regulate solicitations of business or testimonials from persons vulnerable to undue influence, and ban solicitation of testimonials from current psychotherapy patients. The association is permitted to require disclosure of fees that psychologists pay to patient referral services.
- 5. Connecticut Chiropractic Association, 114 F.T.C. 708 (1991) (consent order). The complaint charged that an association of chiropractors unreasonably restrained competition by prohibiting its members from offering free services, or services at discounted fees; advertising in a manner that the association considers to be "undignified" and not in "good taste;" and implying that they possess "unusual expertise." The order prohibits the association from prohibiting, regulating, or interfering with truthful, nondeceptive advertising, including offers of free services, services at discounted fees, and claims of unusual expertise, except that the association may

restrict claims of specialization under certain circumstances.

- 6. Tarrant County Medical Society, 110 F.T.C. 119 (1987) (consent order). The complaint charged that a county medical society in Texas illegally conspired to restrain competition among its members through its Board of Censors, which restricted the amount, duration, and size of advertising announcements in newspapers, and the size and number of telephone directory listings by its members. The order prohibits the society from restricting its members from engaging in truthful advertising.
- 7. <u>Michigan Optometric Association</u>, (See Section II C for citation and annotation.)
- 8. Oklahoma Optometric Association, (See Section II B for citation and annotation.)
- 9. American Academy of Optometry, Inc., (See Section II C for citation and citation.)
- 10. Michigan Association of Osteopathic Physicians & Surgeons, 102 F.T.C. 1092 (1983) (consent order). The complaint charged that a medical society engaged in unlawful concerted action to restrain competition among its members by adopting and enforcing ethical guidelines that unreasonably prevented or hindered its members from soliciting business by truthful advertising or similar means. By virtue of these restraints, members were prohibited from advertising, among other things, fees, acceptance of Medicare or credit cards, professional training and experience, hours and office locations, and knowledge of languages. The order prohibits the medical association from restricting its members from truthfully advertising or soliciting business.
- 11. Washington, D.C. Dermatological Society, 102 F.T.C. 1292 (1983) (consent order). The complaint charged that a medical society engaged in unlawful concerted action to restrain competition among its members by adopting and enforcing ethical guidelines that unreasonably prevented or hindered its members from soliciting business by truthful advertising. By virtue of these restraints, members had been prohibited from advertising, among other things, prices, fees, types or methods of treatment, professional training, experience, special expertise, and the identity, fees, or services of physicians associated with HMOs. The order prohibits the medical society from restricting its members from truthfully advertising or soliciting business.
- 12. **Broward County Medical Association**, 99 F.T.C. 622 (1982) (consent order). The complaint charged that a medical association in Florida engaged in unlawful concerted action to restrain competition among its members by adopting and enforcing ethical guidelines that

unreasonably prevented or hindered its members from soliciting business by truthful advertising of fees or services. By virtue of these restraints, members had been prohibited from advertising, among other things, their fees, acceptance of Medicare or credit cards, professional training and experience, hours and office locations, and knowledge of foreign languages. The order prohibits the medical association from restricting its members from truthfully advertising or soliciting business.

- 13. **Association of Independent Dentists**, (See Section II B for citation and annotation.)
- 14. <u>American Dental Association</u>, 94 F.T.C. 403 (1979) (consent order) (modified 100 F.T.C. 448 (1982) and 101 F.T.C. 34 (1983)). The complaint charged that the ADA illegally engaged in concerted action to restrain competition among its members by adopting and enforcing provisions in its code of ethics that unreasonably prevented or hindered its members from soliciting business by truthful advertising or similar means. The order prohibits the ADA from restricting its members from truthfully advertising or soliciting business.
- 15. **American Medical Association**, (See Section II B for citation and annotation.)
 - 2. State Board Restraints
- 1. Texas Board of Chiropractic Examiners, 115 F.T.C. 470 (1992) (consent order). The complaint charged that a state chiropractic board illegally conspired to restrain competition among chiropractors through its rules that unreasonably restricted chiropractors from engaging in various forms of nondeceptive advertising and solicitation. The order prohibits the board from restricting truthful advertising. The Board may adopt and enforce reasonable advertising rules to prohibit advertising that the Board reasonably believes to be false, misleading or deceptive within the meaning of state law, and to prohibit oppressive in-person solicitation.
- 2. Massachusetts Board of Registration in Optometry, 110 F.T.C. 549 (1988). The Commission decision held that a state optometric board illegally conspired to restrain competition among optometrists, by promulgating and enforcing regulations that prohibited optometrists from truthfully advertising price discounts, that prohibited optical and other commercial establishments from advertising the names of optometrists or the availability of their services, and that prohibited the use of testimonial or sensational advertisements. The Commission found that the regulations were not protected by the state action doctrine because state law did not embody a clearly articulated policy to prohibit optometrists from truthfully advertising discounts, fees, or other information. Under the order, the Board is prohibited from

restraining truthful advertising but may adopt and enforce reasonable rules to restrict fraudulent, false, deceptive, or misleading advertising within the meaning of state law.

- 3. Wyoming State Board of Chiropractic Examiners, 110 F.T.C. 145 (1988) (consent order). The complaint charged that a state chiropractic board engaged in unlawful concerted action to restrain competition among chiropractors by adopting rules that prohibited virtually all telephone directory advertising (with the exception of a practitioner's name, address and two additional descriptive lines of information), and other forms of truthful advertising, including advertising about fees or free consultations or examinations. The challenged rules also encouraged chiropractors to agree on the methods of advertising in their areas. The order prohibits the Board from restricting truthful advertising. Under the order, the Board may adopt and enforce reasonable rules to restrict false or deceptive advertising within the meaning of state law.
- 4. **Brief of the Federal Trade Commission as Amicus Curiae in Parker v. Kentucky Board of Dentistry**, 818 F.2d 504 (6th Cir. 1987). In a case where a dentist challenged the constitutionality of the Kentucky Board of Dentistry's advertising restrictions, which allowed the Board to prohibit the use of terms such as "orthodontics," "braces," and "brackets" in advertisements by general dentists, the Commission filed an amicus brief arguing that such advertisements were not misleading and, therefore, could not be prohibited by the state under the First Amendment. The Commission also argued that there are strong public policy reasons for allowing truthful advertising by professionals, and that unnecessary restrictions on such advertising hinder competition as well as the flow of useful consumer education. The court ruled that the board's outright ban was unconstitutional.
- 5. Wyoming State Board of Registration in Podiatry, 107 F.T.C. 19 (1986) (consent order). The complaint charged that a state podiatric board engaged in unlawful concerted action to restrain competition among podiatrists by restricting most forms of truthful advertising (permitting advertising of little more than name, address, and phone number), and the use of certain advertising media. State law authorized the Board only to regulate the use of untruthful or improbable statements in advertisements. The order prohibits the Board from restricting truthful advertising.
- 6. Montana Board of Optometrists, 106 F.T.C. 80 (1985) (consent order). The complaint charged that a state optometric board engaged in unlawful concerted action to restrain competition among optometrists by restricting optometrists from truthfully advertising prices, terms of credit, down payments, periodic payments, professional superiority, or from using the expression "Contact Lens Clinic" or "Vision Center". State law authorized the Board to regulate only the use of untruthful or ambiguous advertising, and prohibited only the use in

advertisements of the expression "eye specialist" or "specialist in eye" in connection with the name of an optometrist. The order prohibits the Board from restricting truthful advertising. Under the order, the Board may adopt and enforce reasonable rules to implement state law.

7. Louisiana State Board of Dentistry, 106 F.T.C. 65 (1985) (consent order). The complaint charged that a state dental board engaged in unlawful concerted action to restrain competition by restricting dentists from truthfully advertising the prices of their services, particularly discounts. After litigation commenced, the Board entered a consent agreement. Under the order, the Board cannot restrict truthful advertising, but may adopt and enforce reasonable rules, including affirmative disclosure requirements, to restrict false, deceptive, or misleading advertising within the meaning of state law.

F. Illegal Tying and Other Arrangements

- Home Oxygen and Medical Equipment Co., 118 F.T.C. 661 (1994) order set aside for 1. John E. Sailor (retirement from medical practice) 122 F.T.C. 278 (1996), Home Oxygen Pulmonologists, 118 F.T.C. 685 (1994), and Homecare Oxygen and Medical Equipment Co., 118 F.T.C. 706 (1994) (consent orders). The complaint charged that physician-investors, who created joint ventures to provide home oxygen delivery services that are ancillary to the physicians' professional practices, obtained market power, created barriers to entry, and restrained competition in the market for home oxygen systems in Alameda and Contra Costa counties in California. The home oxygen systems are almost invariably prescribed by, or under the direction of, a lung specialist, or pulmonologist and, according to the complaint, approximately 60 percent of the pulmonologists in the relevant geographic markets were recruited as investors in the joint ventures, which were set up as partnerships. The complaint also alleged that by bringing together so many of the physicians who could influence patient choice, the partnerships had market power in the market for pulmonary services, and had the ability to influence patients' choice of oxygen suppliers, through a variety of means. The order prohibits the physicians from acquiring or granting an ownership interest in a firm that sells or leases home oxygen systems in the relevant geographic markets if more than 25 percent of the pulmonologists in the market are affiliated with the firm.
- 2. Sandoz Pharmaceuticals Corporation, 115 F.T.C. 625 (1992) (consent order). The complaint charged that Sandoz unlawfully required those who purchased its schizophrenia drug, clozapine (the first new drug for the treatment of schizophrenia in more than 20 years), to also purchase distribution and patient-monitoring services from Sandoz. Blood monitoring of patients taking clozapine is required to detect a serious blood disorder caused by the drug in a small percentage of patients. The complaint alleged that this illegal "tying" arrangement raised the price of clozapine treatment and prevented others such as private laboratories, the

Veterans Administration, and state and local hospitals – from providing the related blood tests and necessary patient monitoring. The order prohibits Sandoz from requiring any purchaser of clozapine, or a patient taking clozapine, to buy other goods or services from Sandoz. The order guards against the possibility that Sandoz might restrict other firms that want to market generic clozapine in the United States after Sandoz's exclusive selling right expires in 1994, by requiring Sandoz to provide information on reasonable terms if any company is in need of information about patients who have had adverse reactions to the drug. The order also requires Sandoz to not unreasonably withhold information from researchers studying the medical aspects of clozapine use.

3. Gerald S. Friedman, M.D., 113 F.T.C. 625 (1990) (consent order). The complaint charged that a physician who owned and operated dialysis services in Upland and Pomona, California engaged in an illegal tying arrangement, requiring physicians who used his outpatient dialysis facilities to use his inpatient dialysis services when their patients were hospitalized. The complaint alleged that Dr. Friedman had market power in outpatient services, but could not exploit it because Medicare (the dominant purchaser of chronic dialysis services) limits the amount of reimbursement available for outpatient services. Medicare does not, however, set reimbursement amounts for inpatient dialysis. Consequently, the complaint alleges, Dr. Friedman used the tying arrangements to circumvent Medicare's price regulation and charge higher than competitive prices for the tied inpatient services. Under the order, Dr. Friedman agreed 1) not to require any physician to use his inpatient dialysis service for the physician's patients as a condition for using Dr. Friedman's outpatient dialysis facilities; 2) not to bar physicians who want to treat their patients at Dr. Friedman's outpatient dialysis facilities from owning or operating a competing inpatient dialysis service; and 3) not to deny or otherwise impair a physician's staff privileges at one of his outpatient dialysis facilities because that physician has used or operated an inpatient dialysis service other than Dr. Friedman's.

G. Restrictions on Access to Hospitals

- 1. **<u>Diran Seropian, M.D.</u>** (See Section II C for citation and annotation.)
- 2. <u>Medical Staff of Broward General Medical Center</u> (See Section II C for citation and annotation.)
- 3. <u>Medical Staff of Holy Cross Hospital</u> (See Section II C for citation and annotation.)
- 4. North Carolina Orthopaedic Association (See Section II C for citation and annotation.)

- 5. **Eugene M. Addison, M.D.** (See Section II C for citation and annotation.)
- 6. Medical Staff of Memorial Medical Center (See Section II C for citation and annotation.)
- 7. **Health Care Management Corp.** (See Section II C for citation and annotation.)
- 8. **Sherman A. Hope, M.D.** (See Section II C for citation and annotation.)
- 9. **Forbes Health System Medical Staff** (See Section II C for citation and annotation.)
- 10. Brief of the United States and Federal Trade Commission as Amicus Curiae on Petition for Writ of Certiorari, Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 2 (1984). Hyde concerned whether a contract for a single group of anesthesiologists to provide exclusive anesthesia services to a Louisiana hospital was per se illegal under the Sherman Act, as a "tie in" of surgical and anesthesia services. The Department of Justice and the Commission filed an amicus brief arguing that exclusive contracts should be judged under the rule of reason rather than under the per se standard, because such contracts may enhance competition among hospitals and among anesthesiologists, and because the allegedly tied products are normally used as a unit. The Supreme Court ruled that the answer to the question whether one or two products are involved turns not on the functional relationship between them (i.e., not on whether it is a functionally integrated package of services), but rather on the character of the demand for the two items. Per se condemnation is appropriate only if the seller is able to "force" the tied product onto buyers by virtue of its market power. The Court ruled that because the record did not contain evidence that the hospital forced anesthesiology services on unwilling patients, there was no basis for applying the per se rule against tying to the exclusive contract arrangement at issue.

III. PHARMACEUTICAL MERGERS

- A. Horizontal Mergers between Direct Competitors
- 3. **Baxter International Inc., and Wyeth Corporation**, C-4068, (consent order issued

February 3, 2003) (FTC Commission Actions: February 7, 2003 (www.ftc.gov)). The Commission's complaint charged that Baxter's acquisition of the generic injectable drug business from Wyeth's subsidiary, ESI Lederle, would reduce either current horizontal competition or potential competition in the market for five injectable drugs: propofol, pancuronium, vecuronium, metoclopramide, and new injectable iron replacement therapies (NIIRTs): 1) Baxter, under a supply agreement with GensiaSicor, marketed the only generic version of AstraZeneca's branded propofol Diprivan, an anesthetic preferred for outpatient surgery because of its short duration profile. Wyeth was in the process of seeking FDA approval and was one of two companies most likely to enter the market with its own generic version. The complaint alleged that new entry would be difficult and lengthy. Among other things, the preservatives used in the Baxter marketed propofol and in AstraZeneca's product are patent protected and the manufacturing process complex. In order to preserve the future competition and probable lower prices in the market that would have resulted from the entry of a Wyeth generic propofol, the order required the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company, as well as other requirements to ensure the success of the divestiture; 2) In the market for pancuronium, a long-acting neuromuscular blocking agent used to freeze muscles during surgery and for patients who are mechanically ventilated, Baxter (under an exclusive marketing agreement with GensiaSicor), along with Wyeth, and Abbott were the only suppliers. The complaint alleged that the acquisition would have reduced the number of competitors from three to two, leaving Baxter and Wyeth with a combined market share of 74% after the acquisition. New entry was unlikely because pancuronium was an older drug with limited usage. The order required Baxter to divest its pancuronium assets to GenesiaSicor; 3) Wyeth discontinued its production of vecuronium, an intermediate-acting neuromuscular blocking agent used during surgery or ventilation, in 2001, but planned to relaunch the product. Prior to stopping production, Baxter (under an exclusive supply agreement with GensiaSicor) and Wyeth were the two largest of five vecuronium suppliers and held a 53% combined market share. The complaint charged that the acquisition would eliminate the price competition that would have resulted when Wyeth re-entered the market. The order requires Baxter to divest its vecuronium assets to GenesiaSicor; 4) The acquisition would have combined two of four companies supplying metoclopramide, an antiemetic used in certain types of chemotherapy and other post-operative treatments. Wyeth, manufacturer of the branded version of metoclopramide, and Baxter, the exclusive supplier of GensiaSicor's generic metoclopramide drug, together accounted for over half of the U.S. market. The order requires Baxter to terminate its interests in and divest its assets to GensiaSicor; and 5) The complaint alleged harm to potential competition and/or price competition in the market for NIRTs, including both iron gluconate and iron sucrose, which are used to treat iron deficiency in hemodialysis patients. Baxter and Watson jointly marketed Ferrlecit, one of only two NIIRT's approved for sale in the U.S. Wyeth was the best positioned firm to successfully enter the market. The complaint charged that entry was difficult and lengthy. Among other things, a lack of raw material suppliers and complex manufacturing processes complicate entry. The order requires Baxter to terminate its co-marketing agreement with Watson and provides incentives

for Baxter to proceed with development of Wyeth's iron gluconate product. The Commission also appointed a monitor to ensure Baxter's and Wyeth's compliance with the order.

- Amgen Inc. and Immunex Corporation, C-4956, (consent order issued September 3, 2002) 2. (FTC Commission Actions: September 6, 2002 (www.ftc.gov)). The complaint alleged that Amgen's \$16 billion acquisition of Immunex would lessen direct or potential competition in three highly concentrated biopharmaceutical markets: neutrophil regeneration factors, TNF inhibitors, and IL-1 inhibitors. 1) Amgen's Neupogen and Neulasta and Immunex's Leukine were the only neutrophil regeneration factors approved by the FDA for sale in the U.S. Neutrophil regeneration factors are used to help the immune systems of chemotherapy patients by increasing the production of two types of white blood cells. The order requires that Immunex divest its Leukine product to Schering AG 2) TNF inhibitors are used to treat inflamation in patients having autoimmune diseases by preventing the binding of TNF (a cytokine that promotes inflamation) receptors and proteins. Immunex was one of two companies that marketed TNF inhibitors in the U.S. Amgen, one of three companies that had TNF inhibitors in clinical development for sale in the U.S., planned to launch its product in 2005. The order requires that Amgen license certain patents to Sereno, a Swiss company developing a TNF inhibitor for use in Europe, that block Sereno's ability to market in the U.S. and 3) IL-1 inhibitors are also used to treat inflamation in patients with autoimmune diseases. Amgen manufactured the only IL-1 inhibitor on the market in the U.S. Immunex and Regeneron were the only companies with IL-1 inhibitors in clinical trials; Immunex, however, held several patents that could delay or stop the development and marketing of Regeneron's IL-1 inhibitor. The order requires that Immunex license certain patents to Regeneron that will allow it to develop and bring its product to market.
- 3. FTC v. The Hearst Trust, et. al., Civil Action No. 1:01CV00734 (D.D.C. filed April 5, 2001); Civil Action No. 1:01CV02119 (D.D.C. filed October 11, 2001) (civil penalty action); (FTC Commission Actions: October 11, December 14, 2001, January 9, 2002) (www.ftc.gov)). In a complaint filed in U.S. District Court for the District of Columbia, the Commission charged Hearst and its wholly owned subsidiary, First DataBank Inc., with illegally acquiring a monopoly in the market for electronic integratable drug information databases, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. According to the complaint, the 1998 acquisition of Medi-Span, Inc. allowed First DataBank to institute substantial price increases to its customers for use of the electronic databases which contain clinical, pricing and other information on prescription and non-prescription drugs. The complaint also charged Hearst with violating Section 7A (a) of the Clayton Act, by illegally withholding certain 4(c) documents about the Medi-Span acquisition that were required for pre-merger notification review under the Hart-Scott-Rodino Act. The complaint asked the Court to order Hearst to create and divest a new competitor to replace Medi-Span, and to disgorge the illegally gained profits from the anticompetitive price increases. On December 14,

2001, the Commission voted to approve a proposed settlement that required Hearst to divest the former Medi-Span to Facts and Comparisons and to pay \$19 million in disgorgement of illegal profits to its customers. Commissioners Leary and Swindle issued dissenting statements concerning the disgorgement portion of the order. The district court approved the final order and stipulated permanent injunction on December 18, 2001. The Commission also asked the Department of Justice to file a separate complaint in U.S. District Court seeking civil penalties for Hearst's failure to comply with pre-merger notification reporting requirements. In a final judgment filed on October 11, 2001, Hearst agreed to pay \$4 million in civil penalties. On January 9, 2002, the Commission filed a brief as intervenor opposing the private class plaintiffs' petition for an award of \$5 million in attorney fees which represented 22% of the total direct purchaser settlement payment of \$24 million. The Commission argued that private counsels' fees should be reduced to reflect the minimal legal work and limited incremental value that the private attorneys contributed to the settlement after the Commission had reached a tentative settlement with the parties of \$16 million. On May 21, 2002, the District court ruled that the private attorneys were only entitled to a percentage of the settlement attributable to their efforts in the litigation and reduced their award to \$2.4 million.

4. Glaxo Wellcome plc and Smith Kline Beecham plc, C-3990 (consent order issued January 26, 2001) (FTC Commission Actions: January 23, 30, 2001 (www.ftc.gov)). The Commission's complaint charged that the merger of Glaxo Wellcome (Glaxo) and SmithKline Beecham (SB) would create the world's largest research-based pharmaceutical manufacturer, substantially lessen competition in nine separate pharmaceutical markets, and result in fewer consumer choices, higher prices and less innovation. In six markets the order required divestiture: 1) 5HT-3 antiemetic drugs-Glaxo and SB accounted for 90% of the sales of new generation drugs used in chemotherapy to reduce the incidence of side effects. The order required the divestiture of the worldwide rights of SB's drug Kytril to F. Hoffman LaRoche; 2) the injectable antibiotic ceftazidime – Glaxo and SB were the only two manufacturers of ceftazidime, and Glaxo was the largest of three firms marketing ceftazidime. The order required the divestiture of SB's U.S. rights to manufacture and market ceftazidime to Abbott Laboratories; 3) oral and antiviral drugs for the treatment of herpes, chicken pox and shingles--Glaxo's Valtrex and SB's Famvir were the only second-generation antiviral prescription drugs available on the market, and no other companies have similar products in development. The order required the divestiture of SB's antiviral drug Famvir to Novartis; 4) topical antiviral drugs for the treatment of herpes cold sores—SB's Denavir was the only FDA approved prescription topical antiviral drug sold in the US, and Glaxo, the only potential entrant into the market, was seeking FDA approval to market its European antiviral Zovirex in the U.S. The order required SB to divest Denavir to Novartis; 5) prophylactic vaccines for the treatment of herpes -- Glaxo and SB were the leading two of only a few firms pursuing the development of a preventative vaccine. The order required Glaxo to return to its British collaborator, Cantab Pharmaceuticals, all rights to its technology for the development of a prophylactic herpes vaccine; and 6) over-the counter H-2 blocker acid relief products-Glaxo's Zantac 75 and SB's Tagamet were two of the four branded OTC H-2 acid blockers on the market. The order required the divestiture of Glaxo's U.S. and Canadian Zantac trademark rights to Pfizer.

In three markets the order addressed competitive overlaps with other research and development firms where the merger was likely to result in delay, termination, or failure to develop as a competitor: 1) topoisomerase I inhibitor drugs used to treat certain tumors-- SB's Hycamptin was a second line therapy for non-small cell lung cancers and SB was developing a first line therapy for colorectal and other solid-tumor cancers. Glaxo, through a collaboration with Gilead Sciences, was developing a drug, GI147211C, which would have been in direct competition with SB's Hycamptin. Only one other company manufactured similar anti tumor drugs. The order required Glaxo to assign all of its relevant intellectual property rights and relinquish all of Glaxo's reversionary rights to GI147211C to Gilead Sciences; 2) migraine headache treatment drugs-Glaxo's Immitrex and Amerge were the leading sellers of triptan drugs for the treatment of migraine headache. SB had an interest in another triptan drug, frovatriptan, which was being developed and scheduled for launch by Vernalis Ltd. in the second half of 2001. The order required SB to assign all of its intellectual property rights and relinquish all options to regain control over frovatriptan to Vernalis Ltd; and 3) drugs to treat irritable bowel syndrome-Glaxo owned and was conducting clinical trials on Lotronex, which had been taken off the market because of possible side effects. SB had an option to acquire and market renzapride which was being developed by the British firm Alizyme Therapeutics plc. Because the merger would eliminate one of the few efforts underway to develop a drug for the treatment of irritable bowel syndrome, the order required SB to assign all of its intellectual property rights and relinquish all options to regain control over renzapride to Alizyme.

After the Commission issued the proposed consent agreement, the Commission continued to investigate the potential effects of the merger in the smoking cessation products market where Glaxo sold the prescription drug Zyban, and SB marketed Nicoderm and Nicorette, two over-the-counter nicotine replacement products. On January 23, 2001, the Commission closed the smoking cessation products investigation.

5. Pfizer Inc. and Warner-Lambert Company, C-3957 (consent order issued July 27, 2000) (FTC Commission Actions: July 28, 2000 (www.ftc.gov)). The complaint alleged that Pfizer's acquisition of Warner-Lambert Company would lessen competition in four pharmaceutical markets: 1) antidepressant drugs called selective serotonin reuptake inhibitors (SSRIs) and selective norepinephrine reuptake inhibitors (SNRIs) in which Pfizer manufactured Zoloft, the second largest selling SSRI, and Warner and Forest Laboratories co-promoted Celexa, the fastest-growing SSRI. The order required Warner to end its co-promotion agreement with Forest, return all confidential information regarding Celexa to Forest, maintain the confidentiality of all Celexa marketing information, and prohibited former Warner sales employees involved in

marketing Celexa from selling Zoloft until March 2001; 2) pediculicides or treatments for head lice infestation, in which Pfizer and Warner were the two largest manufacturers and accounted for approximately 60% of the market. The order required Pfizer to divest its brand RID to Bayer Corporation; 3) drugs for treating Alzheimer's disease, in which Pfizer's Aricept and Warner's Cognex were the only two drugs sold in the U.S. for the treatment of Alzheimer's disease. The order required the divestiture of Cognex to First Horizon; and 4) EGFr-tk inhibitors, which are drugs used to treat solid tumor cancers, in which Pfizer and Warner were the two most advanced among four companies developing EGFr-tk inhibitors. The order required Pfizer to return its EGFr-tk inhibitor, CP-358,774, along with its technology and knowhow assets to its development partner OSI, to grant OSI an irrevocable worldwide license to its rights and patents jointly owned with Pfizer, to provide OSI with a manufacturing and supply agreement for the continued supply of CP-358,774 until the transfer of the manufacturing technology to a new manufacturer, and to pay OSIs costs for completing clinical trials on the drug. The order also provided for the appointment of an interim trustee to ensure that the development of CP-358,774 is maintained in the future.

- 6. **FTC v. Cardinal Health, Inc. and FTC v. McKesson Corp.**, 12 F. Supp. 2d 34 (D.D.C. 1998). In 1998, the FTC successfully challenged two mergers involving the nation's four largest drug wholesalers -- McKesson merging with AmeriSource and Cardinal Health with Bergen-Brunswig. If the mergers had been permitted, the two survivors would have controlled over 80% of the prescription drug wholesaling market, significantly reducing competition on price and services. The FTC filed the two actions in district court in March 1998, and the case was litigated for approximately seven weeks during June and July. Judge Sporkin enjoined both acquisitions in a 73-page opinion issued at the end of July.
- 7. Roche Holding Ltd., 125 F.T.C. 919 (1998) (consent order). The complaint charged that Roche's proposed \$11 billion acquisition of Corange Limited would harm competition in two U. S. markets: 1) Thrombolytic agents, which are given to heart attack victims as soon as possible after the onset of symptoms in order to dissolve blood clots. Roche, through its majority ownership in Genentech, and Corange, through its Boehringer Mannheim subsidiary, produced the two safest and most effective thrombolytic agents in the U.S. There were no competitive substitutes for thrombolytic agents, and only one other significantly less effective thrombolytic agent was approved for use in the United States; and 2) DAT reagents, which are chemical antibodies that detect whether an illegal substance is present in a urine sample. Workplace DAT screening is conducted at commercial laboratories with instruments designed to use only workplace DAT reagents, and such drug screening is significantly different than hospital-based screening. The DAT reagent market was highly concentrated, and dominated by three of four producers, including Roche and Corange. The complaint alleged that the acquisition, if consummated, would eliminate actual competition between Roche and Corange in the markets for the research, development, manufacture, and sale of cardiac thrombolytic

agents and of DAT reagents used in workplace testing. The acquisition would increase the likelihood that Roche would unilaterally exercise market power in cardiac thrombolytic agents, and the likelihood of collusion or coordinated action among the remaining firms in the DAT reagents market.

The order required Roche to divest or license all of the assets relating to Corange/Boehringer Mannheim's United States and Canadian cardiac thrombolytic agents business to a Commission-approved buyer. Roche was also required to divest, within 60 days of the final order, Corange/Boehringer Mannheim's worldwide DAT reagents business, and to grant to the purchaser an exclusive, world-wide royalty-free license for DAT reagents. Although the divestitures took place within the required time, the Commission included a "crown jewel" provision that would have required a larger asset divestiture had the more narrowly tailored divestiture not occurred.

- 8. American Home Products Corp., 123 F.T.C. 1279 (1997). The complaint alleged that the acquisition of Solvay's animal health business by American Home Products would harm competition in the U. S. market for three types of "companion animal" vaccines. The acquisition would have given American Home Products a dominant position in the markets for canine lyme vaccines, canine corona virus vaccines, and feline leukemia vaccines, enabling it to unilaterally exercise market power, as well as increasing the likelihood of collusion or coordinated action among the remaining firms. The complaint alleged that American Home Products and Solvay were actual competitors for the three vaccines in the United States; that all three markets were highly concentrated; and that entry into each market was difficult and time consuming, with a number of broad patents governing the manufacture of the three products compounding the difficulty of new entry. The order required American Home Products to divest Solvay's U. S. and Canadian rights to the three types of vaccines to Schering-Plough no later than 10 days after the date on which the order became final. In addition, American Home Products had to provide assistance to Schering-Plough in obtaining United States Department of Agriculture certifications, and to manufacture and supply the three vaccines to Schering-Plough for a period of 24 to 36 months or until Schering-Plough obtained the approvals. The order also included provisions protecting Schering-Plough from patent infringement lawsuits relating to the three vaccines.
- 9. **Baxter International, Inc.**, 123 F.T.C. 904 (1997) (consent order). The complaint alleged that Baxter's acquisition of Immuno International raised competitive problems in both a current goods market, where the two firms were horizontal competitors, and an innovation market, where neither firm produced a current product but both were among the few firms with a chance to enter the market. Both firms manufactured a wide variety of biological products derived from human blood plasma. The complaint alleged that competition in two plasma

products where entry was difficult and time consuming would be harmed: 1) the market for Factor VIII inhibitors for hemophiliacs, which was highly concentrated, as Baxter and Immuno were the only two companies marketing those products in the United States; and 2) the market for fibrin sealants, a product that controls bleeding in surgical procedures, in which there were no current producers in the United States and Baxter and Immuno were two of only a few companies seeking FDA approval for the products. With no other comparable products slated for launch before late 1999, Baxter and Immuno were posed to be the sole entrants in a market with estimated potential U.S. sales of \$200 million. The acquisition would have allowed Baxter to eliminate one of the research tracks and exercise unilateral market power. The order required both divestiture and licensing. In the market for Factor VIII inhibitors, the order required Baxter to divest its Autoplex product to a Commission-approved buyer within four months. The order also required licensure of Baxter's fibrin sealant, and required Baxter to provide the acquirer, Haemacure, with finished product for sale.

- J.C. Penney Company/Eckerd Corporation/Rite Aid, 123 F.T.C. 778, 795 (1997) 10. (consent orders). In October, 1996, Thrift Drug, a subsidiary of J.C. Penny entered into an agreement to purchase 190 drug stores in North and South Carolina from Rite Aid; in November, 1996, Omega Acquisition Corp., another subsidiary of J.C. Penny, entered into an agreement to purchase Eckerd, which owned 1,724 drug stores in thirteen states including North and South Carolina. The complaint charged that the acquisitions would give J.C. Penny a dominant position in Charlotte, Greensboro, and Raleigh-Durham, North Carolina, and Charleston, South Carolina, and allow J.C. Penny to raise prices for pharmacy services to third-party payers. The order required J.C. Penny to divest 161 drug stores: 34 Thrift drug stores in the Charlotte and Raleigh-Durham areas, 110 Rite Aid drug stores in North Carolina, and 17 Rite Aid drug stores in Charleston, South Carolina. The order barred J.C. Penny from acquiring the 127 stores in North and South Carolina until a divestiture agreement approved by the Commission was in place, and in addition, allowed the Commission to appoint a trustee to divest the other 63 drug stores acquired from Rite Aid if the divestitures of the 127 stores were not completed on time. The order also required that the stores be divested to a single pharmacy chain to ensure that the buyer could maintain the size and resources necessary to serve as a competitive pharmacy chain in a PBM's pharmacy network.
- 11. <u>CVS Corporation/Revco</u>, 124 F.T.C. 161 (1997) (consent order); (FTC Press Releases: March 27, 1998 (<u>www.ftc.gov</u>)); Civil Action No. 1:98CV0775 (D.D.C. filed March 26, 1998). The complaint charged that the merger of two large retail drug store chains, CVS and Revco, would give the combined company a dominant position in pharmacy services in Virginia, and in the Binghamton, New York area. According to the complaint, the combined firm would have the ability to increase prices for the sale of retail pharmacy services and restrict services to third-party payers, particularly affecting retail pharmacy networks administered by PBMs which depend on competition among pharmacy chains to keep the cost of pharmacy

services competitive. The order required CVS to divest 114 Revco drug stores in Virginia to Eckerd Corporation, and to divest six Revco drug stores in the Binghamton market to Medicine Shoppe. The order allowed the Commission to appoint a trustee who would have the right to divest all 234 Revco drug stores in Virginia and 11 CVS drug stores in the Binghamton market if the required divestitures were not completed three months after the order was finally approved by the Commission. In addition, CVS and Revco signed an asset maintenance agreement requiring them to preserve the viability and competitiveness of the drug stores to be divested. In March 1998, CVS agreed to pay a \$600,000 civil penalty for violating the asset maintenance agreement, the violation of which resulted in the inability of Eckerd to offer pharmacy services that were competitive with the services offered by the pharmacies CVS retained. According to the complaint which was filed in U.S. District Court for the District of Columbia, CVS removed the pharmacy computers and all access to Revco's online data systems prior to the divestiture of the Virginia pharmacies to Eckerd, and then refused to provide Eckerd with the patient pharmacy files in a computerized format that could be used by Eckerd's online computer system.

- Rite Aid Corporation/Revco D.S., Inc., FTC File No. 961-0020 (preliminary injunction authorized April 17, 1996), (FTC Commission Actions: April 17, 24, 1996, (www.ftc.gov)). On April 17, 1996, the Commission authorized staff to seek a preliminary injunction to block the acquisition of the Ohio based Revco drug store chain by Rite Aid, which is headquartered in Pennsylvania. The complaint charged that the merger of the two largest retail drug store chains in the country would substantially reduce competition for prescription drugs sold in retail pharmacy outlets in numerous geographic areas, including Ohio, Indiana, Maryland, Pennsylvania, Virginia, West Virginia, North Carolina and New York. A week after the Commission's decision to challenge the transaction, Rite Aid notified the Commission that it had abandoned the transaction.
- 13. Rite Aid Corporation/Brooks Pharmacies, FTC File No. 951-0120 (closing letter sent May 31, 1996) (FTC Commission Actions: June 3, 1996 (www.ftc.gov)). In September, 1995, Rite Aid entered into an agreement with the Commission under which it was allowed to acquire several Brooks retail pharmacy stores in Maine from Maxi Drug, Inc. pending completion of the Commission's investigation into possible antitrust violations. As a condition for the Commission agreeing not to challenge the acquisition in federal district court, Rite Aid agreed to maintain the marketability and viability of Rite Aid's and Brooks' pharmacies, and to restore any lost competition in the relevant markets. Rite Aid reached a similar agreement with the Maine Attorney General's Office, which investigated the case jointly with the FTC. The Commission closed its investigation in June, 1996, citing a consent agreement that Rite Aid entered into with the Maine Attorney General requiring Rite Aid to divest pharmacies in three relevant geographic markets in Maine.

- 14. Rite Aid Corporation/LaVerdiere's Enterprises, Inc., 118 F.T.C. 1206 (1994) (consent order), Civil Action No. 1:98CV0484 (D.D.C. filed February 27, 1998),125 F.T.C. 846 (1998) (modifying order). The complaint charged that Rite Aid's acquisition of LaVerdiere would substantially lessen competition and increase the prices for prescription drugs sold in retail pharmacy stores in Bucksport and Lincoln, Maine, and in Berlin, New Hampshire. The order required Rite Aid to divest either its own drug stores or the acquired LaVerdiere drug stores in the three cities to a Commission-approved buyer who would operate the stores in competition with Rite Aid. Rite Aid failed to meet the twelve-month deadline for divestiture, and in February, 1996, the Commission appointed a trustee to divest the drug stores. The trustee found buyers for the Lincoln, Maine store and the Berlin, New Hampshire store, but could not find a buyer for the Bucksport, Maine store. In February, 1998 Rite Aid agreed to pay a \$900,000 civil penalty to settle a Commission civil complaint filed in U.S. District Court for the District of Columbia that it failed to comply with the divestiture terms of the 1994 order. Rite Aid then petitioned the Commission to reopen and modify the 1994 order to eliminate the divestiture requirement for the Bucksport, Maine store because neither Rite Aid nor the trustee had been able to find a buyer. The Commission granted the petition in May, 1998, eliminated the divestiture requirement for the Bucksport store, and substituted prior notification and waiting requirements for the prior approval requirement.
- 15. TCH Corporation, et al., 118 F.T.C. 368 (1994) (consent order). The complaint charged that the merger of two drug store chains, TCH and Payless, would violate the antitrust laws, and lead to higher prices and restricted output in six markets in California, Oregon and Washington: Fort Bragg, Bishop, Mt. Shasta, and Taft, California; Florence, Oregon; and Ellensburg, Washington. TCH already owned the Thrifty drug store chain and Bi-Mart, a chain of membership discount stores. The complaint also alleged that the acquisition would eliminate competition between Thrifty or Bi-Mart and Payless, and increase the likelihood of market control or collusion by Thrifty. The order required TCH to divest to Commission-approved buyers, within one year, the pharmacy business in either the Thrifty, Bi-Mart, or Payless drug stores in the six markets. The order also required TCH to maintain the drugs stores until divested as viable and marketable assets.
- 16. Revco D.S. Inc./Hook-SupeRx, 118 F.T.C. 1018 (1994) (consent order) (FTC Commission Actions: November 1, 1996 (www.ftc.gov)). The complaint charged that the acquisition of the Hook-SupeRx drugstore chain by Revco would substantially reduce competition, raise prices, and reduce service in three markets in Covington, Marion, and Radford, Virginia. The order required Revco to divest either its own pharmacies or the pharmacies acquired from Hook-SupeRx in the three towns within one year, and to maintain the viability of the pharmacies prior to divestiture. The order also provided for the appointment of a trustee if the one year deadline for divestiture was not met. In March, 1995 the Commission approved Revco's divestiture of two Hook-SupeRx pharmacies in Radford. The

Commission appointed a trustee in February, 1996, to divest the pharmacies in Covington and Marion because Revco had failed to meet the divestiture deadline called for in the 1994 order. In November 1996, the Commission approved an application from the trustee to divest the drug stores in Marion and Covington to Horizon Pharmacies Inc.

The Dow Chemical Company, et. al., 118 F.T.C. 730 (1994) (consent order). The complaint alleged that the purchase of Rugby Darby Group Companies, Inc. (Rugby) by Marion Merrell Dow, Inc. (MMD) would substantially lessen competition by creating a monopoly in the U.S. market for dicyclomine capsules and tablets, a medication used to treat irritable-bowel syndrome. According to the complaint, MMD and Rugby competed directly and were the only two FDA approved manufacturers of dicyclomine in the U.S. The order required MMD to license dicyclomine formulations and production technology to a third party within12 months, and to contract manufacture dicyclomine for a third party awaiting FDA approval to sell its own dicyclomine. For a period of ten years, the order also required MMD and its parent Dow Chemical to obtain prior approval of the Commission before acquiring any dicyclomine manufacturing, production, or distribution capabilities.

B. Potential Competition Mergers

- 1. **Baxter International Inc., and Wyeth Corporation** (See Section III A for citation and annotation.)
- 2. <u>Amgen Inc. and Immunex Corporation</u> (See Section III A for citation and annotation.)
- 3. **Cytyc Corp. and Digene Corp.,** FTC File No.0210098 (preliminary injunction authorized June 24, 2002) (FTC Commission Actions: June 24, 2002 (www.ftc.gov). The Commission authorized staff to seek a preliminary injunction that would block the proposed merger of two corporations that manufacture and sell tests used in screening for cervical cancer. Cytyc accounted for 93% of the US market for liquid-based Pap tests used in primary screening for cervical cancer. Only one other company, Tripath Imaging, marketed an FDA-approved liquid-based Pap test, and a few other companies may have entered the market in the future. Digene was the only FDA approved supplier of a DNA-based test for the human papillomavirus (HPV) which is thought to be the cause of cervical cancer. Digene's HPV test was used as a back-up test for equivocal Pap tests but was likely to become a primary screening test, first in conjunction with a liquid Pap test, and then as a stand-alone test. Cytyc was the only company that had FDA approval to market the use of the HPV test from its liquid Pap test samples. If filed in court, the Commission's complaint would have alleged that as a result of the acquisition, Cytyc would be in a position to eliminate Tripath as a competitor by

limiting access to Digene's HPV test, and to prevent the entry of other companies that had plans to sell liquid Pap tests in the future. The Commission also cited concerns that the acquisition would eliminate future competition between Cytyc's liquid Pap test and Digene's HPV test as a primary screening test. Within a week after the Commission's decision to challenge the transaction, Digene terminated its acquisition agreement with Cytyc.

- 4. Glaxo Wellcome PLC and Smith Kline Beecham PLC (See Section III A for citation and annotation.)
- 5. Hoechst AG and Rhone-Poulenc, C-3919 (consent order issued January 18, 2000) (FTC Commission Actions: January 28, 2000 (www.ftc.gov)). The complaint charged that Hoechst's acquisition of Rhone-Poulenc would harm competition in the market for direct thrombin inhibitors, which are drugs used in the treatment of blood clotting diseases. Sales of direct thrombin inhibitors total about \$15 million in the U.S. market. Hoechst sold Refludan, the only direct thrombin inhibitor currently sold in the U.S. market. Rhone-Poulenc was in the final stages of developing its direct thrombin inhibitor, Revasc, which it licensed from Novartis in 1998. According to the complaint, direct thrombin inhibitors are more effective and safer than other available alternatives for treating blood clotting diseases, and Hoechst and Rhone-Poulenc were each other's closest competitors. The complaint charged that the merger eliminated direct competition between Hoechst and Rhone-Poulenc, and in addition, reduced potential competition and innovation competition among researchers and developers of direct thrombin inhibitors. The order required Hoechst to transfer all of Rhone-Poulenc's rights for Revasc to Novartis or some other third party, and to enter into a short term service agreement with the acquirer of Revasc in order to ensure the continued performance of development work on Revasc.
- 6. Zeneca Group PLC, 127 F.T.C. 874 (1999) (consent order). Zeneca's proposed acquisition of Astra raised antitrust concerns based upon potential competition. Zeneca entered into an agreement with Chiroscience Group plc to market and assist in the development of levobupivacaine, a new long-acting local anesthetic being developed by Chiroscience. Long-acting local anesthetics are pharmaceutical products used to relieve pain during the course of surgical or other medical procedures, without the use of general anesthesia, and for certain procedures are the only viable anesthetic. Zeneca proposed to acquire the leading supplier of long-acting local anesthetics, Astra, which was one of only two companies approved by the FDA for the manufacture and sale of these kinds of drugs in the United States. Although Zeneca did not currently participate in the market for long-acting local anesthetics, by virtue of its agreement with Chiroscience, it was an actual potential competitor. The Commission's complaint alleged that the acquisition would result in the elimination of a significant source of new competition.

The consent order required Zeneca to transfer and surrender all of its rights and assets relating to levobupivacaine to Chiroscience no later than 10 business days after the date the Commission accepted the agreement for public comment. The assets to be transferred to Chiroscience consisted principally of intellectual property and know-how, and included all of the applicable patents, trademarks, copyrights, technical information, and market research relating to levobupivacaine. During a transitional period, Zeneca was required to continue carrying out certain ongoing activities relating to the commercialization of levobupivacaine, including manufacturing, regulatory, clinical, development, and marketing activities. Zeneca was also required to divest its approximately three percent investment interest in Chiroscience.

7. Hoechst AG, 120 F.T.C. 1010 (1995) (consent order). The complaint alleged that potential competition would be harmed in four markets if Hoechst, a German pharmaceutical company, acquired Marion Merrill Dow in a \$7.1 billion dollar merger that at the time created the world's third largest pharmaceutical company. The four markets accounted for \$1.4 billion in U.S. sales, and affected hundreds of thousands of consumers who suffered from hypertension, angina, arteriosclerosis, and tuberculosis. The relevant markets all featured current production by one of the merging firms and the potential for the other firm to enter the market with a new product: 1) The largest market was the \$1 billion once-a-day diltiazem market, where MMD's Cardizem CD had a dominant share. Prior to the merger, Hoechst and Biovail were jointly developing Tiazac to compete against Cardizem CD. Although Hoechst returned the rights to Tiazac to Biovail before the merger agreement was finalized, the order also required Hoechst to provide Biovail with a letter of access to toxicology data necessary to secure FDA approval, to return to Biovail and refrain from using any confidential information, and to end and refrain from litigations or citizen petitions regarding Tiazac; 2) Hoechst marketed Trental, the only drug that was currently approved by the FDA for intermittent claudication, a painful leg cramping condition that affects over 5 million people in the U.S. MMD had rights to Beraprost, one of the few drugs in development for this condition before the merger. The order required Hoechst to divest either Trental or Beraprost; 3) MMD marketed Pentasa, one of two oral forms of a drug used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease, which affects over 1 million people in the U.S. Hoechst was one of only a few firms developing a generic form of this drug. Hoechst was required to divest one of the two drugs; 4) MMD marketed a brand of the TB drug rifampin. Hoechst was one of only a few firms developing a generic form of rifampin. Hoechst was required to divest one of the two drugs. In each market, Hoechst was required to divest either the current line of business or the potential new product to a Commission-approved buyer that would develop and market it; and to prevent the deterioration of the assets involved, maintain its research and development efforts at pre-merger planned levels pending divestiture, and provide technical assistance and advice to the purchasers in obtaining FDA approval.

C. Innovation Market Mergers

- 1. **Pfizer Inc. and Warner-Lambert Company** (See Section III A for citation and annotation.)
- 2. **Baxter International, Inc.** (See Section III A for citation and annotation.)
- 3. <u>Ciba-Geigy, Ltd.</u>, 123 F.T.C. 842 (1997) (consent order). The complaint alleged that the merger of Ciba-Geigy and Sandoz would result in an anticompetitive impact on the innovation of gene therapies. The firms' combined position in gene therapy research was so dominant that other firms doing research in this area needed to enter into joint ventures or contract with either Ciba-Geigy or Sandoz in order to have any hope of commercializing their own research efforts. Without competition, the combined entity could appropriate much of the value of other firms' research, leading to a substantial decrease in such research. In addition, there was direct competition between the two companies with respect to specific therapeutic products. At the time of the merger, no gene therapy product was on the market, but potential treatments were in clinical trials. The complaint noted that the first products would not be available until the year 2000, but that the market could grow to \$45 billion by the year 2010. The complaint identified five relevant product markets, all of which were located in the United States. The first relevant market encompassed the technology and research and development for gene therapy overall. The other markets each involved the research and development, manufacture, and sale of a specific type of gene therapy: cancer; graft-versus-host disease (GVHD); hemophilia; and chemoresistance. In the market for overall gene therapy, the complaint alleged that Ciba and Sandoz controlled the key intellectual property rights necessary to commercialize gene therapy products. For each of the four specific gene therapy markets, the complaint asserted that the relevant market was highly concentrated and that Ciba and Sandoz were the two leading commercial developers of the gene therapy product. Moreover, entry into the gene therapy markets was difficult and time-consuming because any entrant would need patent rights, significant human and capital resources, and FDA approvals.

The order centered on the intellectual property rights. The new company, Novartis, was required to grant to all requesters a non-exclusive license to certain patented technologies essential for development and commercialization of gene therapy products. Depending on the patent, Novartis could receive an up-front payment of \$10,000 and royalties of one to three percent of net sales. Novartis also was required to grant a non-exclusive license of certain technology and patent rights related to specific therapies for cancer, GVHD, and hemophilia to a Commission-approved licensee. Novartis could request from the licensee consideration in the form of royalties and/or an equivalent cross-license. Further, the merged company could not acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy.

- 4. The Upjohn Co., 121 F.T.C. 44 (1996) (consent order). The complaint alleged that the acquisition of Pharmacia Aktiebolag by Upjohn would harm competition in the market for topoisomerase I inhibitors, drugs used in conjunction with surgery to treat colorectal cancer. The merging firms were two of only a very small number of companies in the advanced stages of developing the drugs. Upjohn's CPT-11 was the most advanced product, with Pharmacia's 9-AC product a few years behind. Because it would take the other companies years to reach the advanced stage of development, the complaint alleged that it was not likely that other firms would constrain the merged firm from terminating development of one of the products or raising prices. The order required the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.
- 5. Glaxo PLC, 119 F.T.C. 815 (1995). In *Glaxo*, the complaint alleged harm to innovation markets where the merging parties Glaxo and Burroughs Wellcome were the two firms furthest along in developing an oral drug to treat migraine attacks. Current drugs existed to treat migraine, but they were available only in injectable form and were not sufficiently substitutable to be included in the relevant market. The complaint alleged that the acquisition would eliminate actual competition between the two companies in researching and developing migraine remedies. The complaint also alleged that the acquisition would reduce the number of research and development tracks for these migraine remedies, and increase Glaxo's unilateral ability to reduce research and development of these drugs. The order required the combined firm to divest Wellcome's assets related to the research and development of the migraine remedy. Among those assets were patents, technology, manufacturing information, testing data, research materials, and customer lists. The assets also included inventory needed to complete all trials and studies required to obtain FDA approval.

D. Vertical Mergers

- 1. Merck & Co., Inc., 127 F.T.C. 156 (1999) (consent order). The complaint alleged that Merck's ownership of Medco, a pharmacy benefits manager ("PBM"), would allow Merck to favor its own drugs on Medco's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order requires Merck/Medco to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee.
- 2. <u>Eli Lilly/PCS</u> 120 F.T.C. 243 (1985) (consent order); 127 F.T.C. 577 (1999) (set aside order). The complaint alleged that Lilly's acquisition of PCS, a pharmacy benefits manager ("PBM"), from McKesson Corp. would allow Lilly to favor its own drugs on PCS's formularies. A PBM's formulary often affects drug choice and reimbursement under certain

health plans. The order requires Lilly/PCS to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee. The order was set aside in 1999 because Lilly sold PCS to Rite Aid Corp.

IV. MERGERS OF HEALTH CARE PROVIDERS

A. General Acute Care Hospitals

FTC, et al., vs. Tenet Healthcare Corp., et al., D. 9289; No. 98-3123EML, 17 F. Supp. 1. 2nd 937 (E.D. Mo. 1998); rev'd 186 F.3d 1045 (8th Cir. 1999). On April 16, 1998, the Commission authorized the filing of a motion for a temporary restraining order and preliminary injunction, pending the outcome of an administrative trial, to block the acquisition of 230 bed Doctors Regional Medical Center in Poplar Bluff, Missouri, by Tenet Healthcare Corp. Tenet, the second largest for-profit hospital system in the United States, already owned 201 bed Lucy Lee Hospital, the only other general acute care hospital in Popular Bluff. According to the Commission complaint, filed in U.S. District Court for the Eastern District of Missouri, Eastern Division, the merger of the two general acute care hospitals, having approximately 78% of the market for acute-care inpatient services in Popular Bluff, would create a virtual monopoly for acute care inpatient services, eliminate substantial competition between the two hospitals, and provide the merged party with the ability to exercise market power. The Commission was joined in its suit in district court by the Missouri Attorney General's office. On July 30, 1998 the judge issued a preliminary injunction pending the completion of an administrative trial. In granting the preliminary injunction, the judge agreed with the geographic market identified by the Commission and ruled that the FTC was likely to succeed on the ultimate issue of whether the merger would have the effect of substantially lessening competition. According to the district court decision, the benefits to consumers and efficiencies encouraged by the intense competition between the two hospitals, which had directly competed for managed care contracts, would be eliminated if the merger were allowed to proceed. The defendants appealed to the Eighth Circuit and on July 22, 1999, the appeals court reversed the district court's decision. The Eighth Circuit found that the Commission failed to prove its geographic market, and therefore could not show that the merged parties would possess market power. In October, 1999, the Eighth Circuit denied petitions by the FTC and State of Missouri for a rehearing en banc, and denied the Commission's motion to stay the mandate. On October 27, 1999, Justice Thomas denied an emergency motion to stay the mandate. On December 3, 1999, the Commission "determined not to seek further review of the Court of Appeals decision." The Commission dismissed the administrative complaint on December 23, 1999.

2. Tenet Healthcare Corporation/OrNda Healthcorp, 123 F.T.C. 1337 (1997) (consent

order). The Commission issued a consent agreement settling charges that the acquisition of OrNda Healthcorp by Tenet Healthcare Corp. would substantially lessen competition for general acute care services in the San Luis Obispo, California area. Tenet and OrNda were the second and third largest chains of general acute care hospitals in the country, and the two leading providers of acute care hospital services in San Luis Obispo County. Tenet owned 195-bed Sierra Vista Regional Medical Center in San Luis Obispo, and 84-bed Twin Cities Community Hospital in Templeton; OrNda owned 147-bed French Hospital Medical Center in San Luis Obispo. OrNda also owned 70-bed Valley Community Hospital in Santa Maria, about 30 miles south of the city of San Luis Obispo and just south of San Luis Obispo County. According to the complaint, the combination of the three largest of the five hospitals in San Luis Obispo County would eliminate competition between Tenet and OrNda, significantly increase the high level of concentration for acute care hospital services, and increase the market share of Tenet to over 71%.

The order required Tenet to divest French Hospital Medical Center and other related assets in San Luis Obispo County, to an acquirer approved by the Commission, by August 1, 1997. Tenet was also required to divest its stock in Monarch Health Systems, an integrated health delivery system operating in San Luis Obispo and Santa Barbara counties, which was one third owned by OrNda and was a major customer of French Hospital. For a period of ten years after the order is made final, Tenet must notify the Commission before combining its acute care-hospitals in San Luis Obispo County with any other acute care hospital in that area, or acquiring Monarch stock. In addition, for a period of ten years, the acquirer of French Hospital must notify the Commission before selling the hospital to anyone owning another acute care hospital in San Luis Obispo County. The FTC did not challenge the merger in any other markets. This matter involves the same market and the same principal hospitals at issue in a previous Commission hospital merger case, American Medical International, Inc. (discussed below), which also resulted in the divestiture of French Hospital.

3. FTC v. Butterworth Health Corp., D.9283; 124 F.T.C. 424 (1997) (Order granting motion to dismiss); 1996-2 Trade Case ¶71,571 (W.D. Mich); 1997-2 Trade Case ¶71,863 (6th Cir.) (Sixth Circuit Rule 24 limits citation to specific situations). On January 19, 1996, the Commission authorized the filing of a preliminary injunction to block the combination of the two largest acute care hospitals in Grand Rapids, Michigan, 529-bed Butterworth Hospital and 328-bed Blodgett Memorial Medical Center. The complaint alleged that the merger would substantially lessen competition in the provision of general acute care hospital services in the greater Kent County, Michigan area, and primary care inpatient hospital services in the immediate Grand Rapids area. The district court judge denied the request for a preliminary injunction on September 26, 1996, ruling that although the FTC had properly identified the alleged product and geographic markets, and demonstrated that the merged party would have substantial market power in the relevant markets, the Commission had failed to show that the

merged non-profit entity would exercise its market power to harm consumers. On November 18, 1996, the Commission voted to appeal the district court decision, and issue an administrative complaint. In an unpublished decision, the Sixth Circuit Court of Appeals affirmed the district court on July 8, 1997, finding that the district court did not abuse its discretion in denying preliminary relief. On September 26, 1997, the Commission dismissed the administrative complaint on the grounds that further litigation was not in the public interest.

- 4. Columbus Hospital/Montana Deaconess Medical Center, FTC File No. 951-0117 (closing letter sent June 28, 1996). This matter involved the merger of Columbus Hospital and Montana Deaconess Medical Center, the only two general acute care hospitals in Great Falls, Montana. The closing letters stated that although the transaction raised significant antitrust concerns, the Commission closed this investigation in light of regulatory involvement by the state of Montana. The Montana legislature enacted a statue providing that a "certificate of public advantage" (COPA) issued by the Montana State Department of Justice signaled the state's intent to "substitute state regulation for competition." The COPA issued for this merger included comprehensive price controls, including a patient revenue cap, conditions relating to the quality of hospital care, and conditions concerning the hospitals' dealings with health plans, physicians, competitors, and ancillary service providers. The regulations also involved ongoing enforcement of the regulatory scheme.
- 5. FTC v. Local Health System, Inc., 120 F.T.C. 732 (1995) (consent order); No. 94 CV 74798 (E.D. Mich.) (Preliminary injunction suit filed November 30, 1994). On November 9, 1994, the Commission authorized the staff to seek a preliminary injunction to block the combination of the only two general acute care hospitals in Port Huron, Michigan. The matter involved the proposed merger of non-profit Port Huron Hospital and non-profit Mercy hospital-Port Huron, and the creation of a new non-profit corporation, Lakeshore Health System, Inc. Soon after the court proceedings were begun, the parties elected to call off their proposed merger, and the court proceedings were put on hold pending settlement discussions. On October 3, 1995, the Commission accepted a consent order, which for three years required prior Commission approval before the parties carried out any renewed attempt to merge their operations, and for ten years required prior notice to the Commission of any significant combination of their hospitals with each other or with hospitals belonging to third parties.
- 6. **FTC v. Freeman Hospital**, D.9273; 911 F. Supp.1213 (W.D. Mo. 1995), aff'd 69 F.3d 260 (8th Cir. 1995). This matter involved the merger of Freeman and Oakhill hospitals, the second and third largest acute care hospitals in Joplin, Missouri. A preliminary injunction suit was filed and orally dismissed on February 22, 1995 (dismissed by written order, February 28, 1995); the dismissal was stayed by order of the Eighth Circuit on March 1, 1995, enjoining

further consolidation and retaining jurisdiction pending an evidentiary hearing. The district court on June 6, 1995 denied the Commission's request for a preliminary injunction; on November 1, 1995, the Eighth Circuit Court of Appeals affirmed the district court's decision, finding that the Commission had failed to show that the relevant geographic market was what the Commission had alleged. On December 1, 1995, the Commission voted to dismiss the administrative complaint after concluding that further litigation was not in the public interest.

7. Columbia/HCA Heathcare Corporation/Heathtrust, Inc. - The Hospital Company, 120 F.T.C. 743 (1995) (consent order); 124 F.T.C. 38 (1997) (modifying order); Civil Action No. 1:98CV01889 (D.D.C. filed July 30, 1998) (order violation final judgement). The complaint alleged that Columbia/HCA Healthcare Corporation's (Columbia/HCA) planned acquisition of Healthtrust, Inc. - The Hospital Company (Healthtrust) would substantially lessen competition for general acute care hospital services in six geographic markets. Columbia/HCA and Healthtrust are the two largest chains of general acute care hospitals in the country. According to the complaint, Columbia/HCA and Healthtrust are competitors in six areas that are relevant geographic markets: the Salt Lake City - Ogden Metropolitan Statistical Area, Utah; the Denton, Texas, area; the Ville Platte-Mamou-Opelousas, Louisiana, area; the Pensacola, Florida, area; the Okaloosa, Florida, area; and the Orlando, Florida, area. In each of these areas, the market for acute care inpatient hospital services is highly concentrated, whether measured by Herfindahl-Hirchsman Indices (HHI) or by four-firm concentration ratios, and entry is difficult due to state certificate of need regulations, substantial lead times required to establish a new acute care hospital, and other factors.

Healthtrust was under a prior Commission order, issued in Healthtrust, Inc. - The Hospital Company (discussed below). That order required Healthtrust to obtain prior Commission approval before transferring hospitals it owned in the Salt Lake City - Ogden Metropolitan Statistical Area, to anyone who operated other hospitals in that same area. Columbia/HCA already operated hospitals in that area. Healthtrust applied for prior approval to transfer the four hospitals it owns in that area to Columbia/HCA, conditioned upon Columbia/HCA subsequently divesting three hospitals (two owned by Healthtrust and one by Columbia/HCA). At the same time the Commission accepted the consent agreement for public comment, it granted prior approval to Healthtrust to transfer the four Salt Lake City - Ogden Metropolitan Statistical Area hospitals to Columbia/HCA, subject to the subsequent divestitures.

Under the consent order, Columbia/HCA was required to divest seven hospitals within twelve months to a purchaser approved by the Commission. Columbia/HCA agreed to divest a single hospital in each of four of the geographic markets: the Denton, Texas, area; the Ville Platte-Mamou-Opelousas, Louisiana, area; the Pensacola, Florida, area; and the Okaloosa,

Florida, area. Columbia/HCA also was ordered to divest three hospitals in the Salt Lake City - Ogden Metropolitan Statistical Area, to a purchaser approved by the FTC, within nine months of the Commission granting Healthtrust's application for prior approval. For a period of ten years, Columbia/HCA must notify the Commission before either acquiring another acute care hospital in any of the relevant geographic markets, or transferring an acute care hospital to anyone operating another acute care hospital in the same relevant geographic market. In addition, for a period of ten years, the acquirer of each of the divested acute care hospitals must notify the Commission before selling the facility to anyone owning another acute care hospital in the same relevant geographic market.

In addition, Columbia/HCA was ordered to terminate a joint venture in the Orlando, Florida, area. Healthtrust and Orlando Regional Health System (ORHS) jointly owned and operated the South Seminole Hospital, in Longwood, Florida. ORHS operated four hospitals in the Orlando area in addition to its partnership interest in South Seminole Hospital. The interest in the South Seminole Hospital was Healthtrust's sole hospital in the Orlando area. Columbia owned four other hospitals in the Orlando area. The complaint alleged that Columbia/HCA's acquisition of Healthtrust's interest may increase the likelihood of collusion or interdependent coordination by the remaining firms in the market, because the South Seminole Hospital would be jointly owned by Columbia/HCA and ORHS. Columbia/HCA was ordered to terminate the joint venture within six months after the order becomes final, either by buying out ORHS' interest in the joint venture or by selling Healthtrust's interest to a purchaser approved by the FTC.

On July 30, 1998, Columbia agreed to pay a \$2.5 million dollar civil penalty to settle a Commission complaint that it violated the above order concerning Columbia/HCA's acquisition of Healthtrust, and that it also violated the order in Healthtrust, Inc. - The Hospital Company, under which Healthtrust was required to obtain Commission approval before selling any assets to a competitor. After its purchase of Healthtrust, Columbia/HCA was bound by the earlier Healthtrust order. Columbia/HCA, when it violated the 1995 order, failed to satisfy the conditions under which the Commission had granted prior approval to the acquisition of Healthtrust. In its complaint filed in U.S. District Court for the District of Columbia, the FTC charged that Columbia/HCA did not complete the divestiture of South Seminole Hospital until September of 1997, while the order required it to do so by April 1996. The complaint further charged that Columbia/HCA did not complete the divestiture of Davis and Pioneer Valley hospitals in Utah until May of 1996, while the order required that it do so by January 1996. The complaint also charged that Columbia/HCA did not hold the assets and confidential information of Davis and Pioneer Valley hospitals separate between the hospitals and Columbia/HCA, as required by the order.

- 8. FTC v. Columbia Hospital Corporation 117 F.T.C. 587 (1994)(consent order); 126 F.T.C. 192 (1998) (modifying order substituting a prior notice provision for the prior approval requirement); No. 93-30-FTM-CIV-23D (M.D. Fla., preliminary injunction issued May 21, 1993). The Commission's administrative complaint charged that the proposed acquisition by for-profit Columbia Hospital Corporation of Adventist Health System's non-profit Medical Center Hospital in Punta Gorda, Florida would significantly increase already high levels of concentration in the Charlotte County area by eliminating competition between Medical Center and Fawcett Memorial Hospital, a hospital in Port Charlotte, Florida, already owned by Columbia. On February 1, 1993, the Commission filed a preliminary injunction suit in the Middle District of Florida, and the State of Florida filed an affidavit supporting the Commission's suit. The district judge issued a temporary restraining order until he could rule on the motion for a preliminary injunction. The judge granted that motion May 5, and entered a stipulated preliminary injunction (without right of appeal) on May 21. Columbia called off its proposed acquisition. The Commission's consent order, which concluded the administrative proceedings, prohibits Columbia from merging its hospital in the Charlotte County area with Medical Center or any other hospital in that area, unless it obtains prior Commission approval. Columbia also must give the Commission advance notice of certain joint ventures with the other Charlotte County hospitals.
- 9. Columbia Healthcare Corporation/HCA-Hospital Corporation of America, 118 F.T.C. 8 (1994) (consent order);126 F.T.C. 160 (1998) (modifying order substituting a prior notice provision for the prior approval requirement). The complaint charged that the merger of Columbia Healthcare Corporation and HCA-Hospital Corporation of America, two large forprofit hospital chains, may substantially lessen competition in the market for general acute care inpatient hospital services in the Augusta, Georgia/Aiken, South Carolina area. According to the complaint, the merger would significantly increase the already high level of concentration in the market, and could enhance the possibility of collusion or interdependent coordination by the remaining firms in the market.

Under the consent order, Columbia was required to divest Aiken Regional Medical Center in Aiken, South Carolina, within twelve months after the order became final to a purchaser approved by the FTC. Columbia also was required to hold Aiken Regional separate from its other operations, and to maintain its marketability and viability as an independent competitor in the market until the divestiture was completed. Columbia also was prohibited, for ten years, from merging its remaining hospital in the market (Augusta Regional Medical Center in Augusta, Georgia) with any other acute care hospital in the market without the FTC's prior approval. The FTC did not challenge the merger in any other markets.

10. **Dominican Santa Cruz Hospital**, 118 F.T.C. (1994) (consent order). The complaint

charged that non-profit Dominican Santa Cruz Hospital in Santa Cruz, California, and its parent Catholic Health Care West, violated Section 7 of the Clayton Act when they acquired for-profit Community Hospital of Santa Cruz. That acquisition was completed in 1990 (no premerger notification was required). Dominican and Community were the only two general hospitals in Santa Cruz, and there was only one other general hospital in the Santa Cruz metropolitan area. The complaint alleged general acute care hospital services within that area to be the relevant market, and that market already to have been highly concentrated and difficult to enter prior to the acquisition. The order does not require Dominican or Catholic Health Care West to divest Community Hospital, but prohibits them from acquiring all or any significant part of any other general hospital in the relevant market within the next ten years, unless the Commission gives prior approval to the transaction.

- 11. Parkview Episcopal Medical Center/St. Mary-Corwin Hospital, File No. 931-0025 (preliminary injunction authorized January 31, 1994). On January 31, 1994, the Commission authorized the staff to seek a preliminary injunction to block the combination of the only two general acute care hospitals in Pueblo County, Colorado. The matter involved the proposed acquisition of nonprofit Parkview Episcopal Medical Center by nonprofit St. Mary-Corwin Hospital and its corporate parent Sisters of Charity Health Care Systems. Several days after the Commission's decision to challenge the transaction, the parties announced they had abandoned the transaction.
- 12. Adventist Health System/West, 117 F.T.C. 224 (1994). This matter concerned the 1988 acquisition of a for-profit hospital in Ukiah, California by a non-profit hospital chain which already operated a hospital in that community. The FTC issued its complaint challenging the acquisition in late 1989, alleging that the acquisition endangered competition by giving the hospital chain dominance of the local general acute care hospital services market (with a market share exceeding 70%, and only one or two competitors left after the acquisition). An FTC administrative law judge dismissed the complaint, finding that the Commission lacked jurisdiction over the challenged acquisition because it was not covered by Section 7 of the Clayton Act. In August 1991, the Commission unanimously reversed the ALJ's decision and sent the case back to the ALJ for trial on the merits, holding that Section 7's "asset acquisition" clause covers acquisitions by non-profit entities. On December 9, 1992, the administrative law judge dismissed the complaint on the merits, finding the acquisition not likely to be anticompetitive. On April 15, 1994, the Commission dismissed staff's appeal to the Commission, concluding that complaint counsel had not proven the geographic market alleged in the complaint, or that the acquisition would be anticompetitive in a larger market. Two Commissioners issued concurring opinions concerning the lack of evidence of anticompetitive effects resulting from the merger.

- 13. Healthtrust, Inc. - The Hospital Company/Holy Cross Health Services of Utah, 118 F.T.C. 959 (1994) (consent order); 126 F.T.C. 170 (1998) (modifying order substituting a prior notice provision for the prior approval requirement); Civil Action No. 1:98CV01889 (D.D.C. filed July 30, 1998) (order violation final judgement) (see Columbia/HCA-Healthtrust above). On March 22, 1994, the Commission authorized its staff to seek a preliminary injunction to block the acquisition by Healthtrust of three hospitals in the Salt Lake City, Utah area. Healthtrust, which owns Pioneer Valley Hospital in West Valley City, and Lakeview Hospital in Bountiful, would have acquired Holy Cross Hospital of Salt Lake City, Holy Cross-Jordan Valley in West Jordan, and St. Benedict's Hospital in Ogden from Holy Cross Health Services of Utah. The FTC staff did not file suit, and instead negotiated a consent agreement to settle the matter. Healthtrust was permitted to acquire the three Holy Cross Health Services hospitals, but was required to divest Holy Cross Hospital of Salt Lake City within six months after the order became final, to a purchaser approved by the FTC. Healthtrust was also required to hold Holy Cross Hospital separate from its other operations, and to maintain its marketability and viability as an independent competitor in the market until the divestiture was completed. The order also prohibited Healthtrust from merging any of its hospitals in Weber, Salt Lake, or Davis counties in Utah with any other general hospital in those counties, absent advance Commission approval, for a period of ten years.
- 14. FTC v. Hospital Board of Directors of Lee County, FTC Docket No. 9265; 1994-1 Trade Case. ¶ 70,593 (M.D. Fla.); aff'd 38 F.3d 1184 (11th Cir. 1994). The Commission issued an administrative complaint, and filed a preliminary injunction suit in Federal court, charging that the proposed acquisition of non-profit Cape Coral Hospital by publicly-owned Lee Memorial Hospital would endanger competition in Lee County, Florida in violation of Section 7 of the Clayton Act. According to the complaints, the merger would significantly increase already high levels of concentration in Lee County by eliminating competition between Cape Coral and Lee Memorial. (The Federal court complaint alleged, as measured by patient admission, the Herfindahl-Hirschman Index would increase by 1775 from 3523 to 5289, and Lee Memorial's market share in Lee County would increase to 67%, as a result of the acquisition.)

The Commission's preliminary injunction suit was filed in the U.S. District Court for the Middle District of Florida on April 28, 1994. The district court judge granted a temporary restraining order until he could rule on the motion for a preliminary injunction. On May 16 the court ruled in favor of defendants on their motion to dismiss based on state action immunity. The Commission appealed that decision to the U.S. Court of Appeals for the Eleventh Circuit. On May 18 that court stayed the district court's order dismissing the Commission's complaint (thereby reinstating the temporary restraining order against completion of the proposed merger), pending consideration of the Commission's appeal. The Court of Appeals on November 30 affirmed the district court's ruling, and thereafter vacated its stay blocking the

merger. The Commission filed a petition for rehearing <u>en banc</u>, which was denied on March 9, 1995. The challenged acquisition was called off on February 1, 1995, after Cape Coral entered into a definitive agreement to be acquired by Health Management Associates. The Commission thereafter suggested that the preliminary injunction proceeding was moot, and moved to vacate the appeals and district courts' prior decisions; that motion was denied, as was the Commission's rehearing petition, in March, 1995. On July 7, 1995, the Commission voted not to seek Supreme Court review, bringing to a close the Federal court proceedings.

The Commission's administrative complaint was issued May 6, 1994. The ensuing administrative litigation was stayed pending completion of the federal court litigation. On July 7, 1995, the Commission concluded the administrative proceedings by dismissing the administrative complaint, on the grounds that because of the cancellation of the proposed Lee Memorial-Cape Coral merger, further proceedings to pursue additional relief were not in the public interest.

- 15. Columbia Hospital Corporation/Galen Health Care, Inc., 116 F.T.C. 1362 (1993) (consent order); 126 F.T.C. 150 (1998) (modifying order substituting a prior notice provision for the prior approval requirement). The complaint charged that the merger of Columbia Hospital Corporation and Galen Health Care, Inc., two large for-profit hospital chains, may substantially lessen competition in the market for general acute care inpatient hospital services in the Kissimmee, Florida area, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. According to the complaint, the merger would significantly increase already high levels of concentration in the market, could create a firm whose market share is so high as to lead to unilateral anticompetitive effects, and it could enhance the possibility of collusion or interdependent coordination by the remaining firms in the market. Under the order, Columbia was required to divest Kissimmee Memorial Hospital in Osceola County. The order also prohibits Columbia and Galen from acquiring any other hospital in Osceola County for 10 years without prior FTC approval. Columbia divested Kissimmee Memorial to Adventist Health System/Sunbelt Health Care Corporation without objection from the FTC. The FTC did not challenge the merger in any other markets.
- 16. FTC v. University Health, Inc., 115 F.T.C. 880 (1992) (consent order); 1991-1 trade Cases ¶69,400 (S.D.Ga.) and 1991-1 Trade Cases ¶69,444 (S.D. Ga.), rev'd, 938 F.2d 1206 (11th Cir. 1991). The Commission issued an administrative complaint charging that the acquisition of nonprofit St. Joseph Hospital by nonprofit University Health, Inc., which operated University Hospital, would substantially lessen competition in the market for general acute care hospital services in the Augusta, Georgia, area, in violation of § 7 of the Clayton Act. The Commission complaint charged that, whether measured by the Herfindahl-Hirschman Index or by four-firm concentration ratios, the proposed acquisition would create a hospital whose

market share would be so high as to lead to dominant firm status.

In addition, the Commission filed a preliminary injunction suit on March 20, 1991, in the Southern District of Georgia. The district court denied the preliminary injunction on the merits, but upheld Commission jurisdiction in the matter, in a bench ruling issued on April 4. On appeal by the Commission, the Eleventh Circuit Court of Appeals reversed the district court, and instructed the district court to issue a preliminary injunction. On May 7, 1991, the district court issued an order enjoining consummation of the proposed merger pending the outcome of the Commission's administrative proceedings. The hospitals thereafter called off the transaction.

On July 26, 1991, the Eleventh Circuit issued an unanimous opinion, explaining its reasons for reversal of the district court decision. The Court of Appeals held that the FTC had made a strong <u>prima facie</u> case showing that the proposed acquisition would substantially lessen competition in the Augusta area, and that the failure to grant a preliminary injunction would frustrate the Commission's ability to protect the public from anticompetitive behavior. In granting the injunction, the appeals court affirmed the district court's holding that the FTC may enforce §7 of the Clayton Act against asset acquisitions involving solely non-profit entities. The court also found that Georgia's certificate-of-need law constituted a substantial barrier to the entry of new competitors or to expansion by existing hospitals. The court also rejected arguments presented by the hospitals concerning a "weakened competitor" defense and the non-profit status of the acquiring hospital. Possible efficiencies resulting from the acquisition were found to be too speculative and insubstantial to undermine the Commission's <u>prima facie</u> showing of illegality.

The Commission's administrative proceeding was later settled by consent order. Under the order University 1) was prohibited from acquiring, or being acquired by, any hospital in the Augusta area without prior Commission approval; and 2) was required to notify the Commission before entering into joint ventures with other hospitals in the Augusta area.

The Reading Hospital, 113 F.T.C. 285 (1990) (consent order). The complaint charged that the merger of non-profit Reading Hospital and Medical Center and non-profit Community General Hospital injured consumers by restricting competition in general acute-care hospital services in the Reading, Pennsylvania, area. According to the complaint, the two hospitals were both independent private, non-profit corporations until December, 1985, when they formed a new corporation, Berkshire Health System, to operate the two hospitals. Community General left the Berkshire Health System in January, 1989, and Berkshire was dissolved in December 1989. During the period of consolidation, the complaint alleged that Berkshire controlled two of the three general acute care hospitals in the Berks County area, with a market

share of 77%. The Herfindahl-Hirschmann Index increased from about 4700 to 6500 points based on in-patient days. The complaint alleged that the consolidation eliminated competition between the two hospitals denying patients, physicians, and purchasers of health care coverage the benefits of free and open competition based on price, quality, and service. Under the order, the hospitals, which had already terminated their affiliation, were required to obtain Commission approval before merging with each other or with any other hospital in Berks County, Pennsylvania.

- Hospital Corporation of America, 106 F.T.C. 361 (1985), aff'd, 807 F.2d 1381 (7th Cir. 18. 1986), cert. denied, 481 U.S. 1038 (1987). The Commission decision held that a for-profit hospital chain's acquisition of several competing hospitals in the Chattanooga, Tennessee area violated § 7 of the Clayton Act and § 5 of the FTC Act, because it tended to lessen competition substantially in the market for general acute care hospital services in Chattanooga. The Commission ordered the divestiture of two hospitals and the termination of a management contract with another hospital. The Commission rejected the argument that health care acquisitions were immune from the antitrust laws. The Commission found that Chattanooga hospitals had a history of interaction that facilitated collusion, and that the acquisitions at issue made it more likely that the hospitals could successfully collude to decrease or eliminate competition. After the acquisitions, HCA owned or managed 5 of the 11 hospitals in the Chattanooga urban area. HCA increased its market share in the Chattanooga area from 13.8% to 25.8% measured by inpatient days, from 13.6% to 26.7% measured by approved acute care beds, and from 14.3% to 25.5% measured by net patient revenues. The Herfindahl-Hirschman Index increased from 2028 points to 2467 measured by inpatients days, from 1932 to 2416 measured by approved acute care beds, and from 2220 to 2634 measured by net patient revenues. The Commission holding was affirmed by the Seventh Circuit Court of Appeals.
- 19. Hospital Corporation of America, 106 F.T.C. 298 (1985) (consent order) (modified 106 F.T.C. 609 (1985)). The complaint charged that the acquisition by HCA, a for-profit hospital chain, of hospitals in the Virginia and Texas areas from Forum Group Inc., another for-profit hospital chain, violated § 7 of the Clayton Act and § 5 of the FTC Act because these acquisitions might substantially lessen local market competition in, respectively, the psychiatric hospital services market and general acute care hospital services market. HCA already owned a psychiatric hospital in the Norfolk area, and operated under management contract a large county general hospital near Forum's hospital in Midland. The complaint charged that as a result of the acquisitions, HCA increased its market share of general acute care hospital services in the Texas area from about 50% to about 58% based on licensed general acute care beds, and from about 3530 points to about 4350, based on licensed general acute care beds, and from about 3990 to about 4550 based on inpatient days. The complaint also charged that

as a result of the acquisitions, HCA increased its market share of psychiatric hospital services in the Norfolk, Virginia, Metropolitan area from about 15% to about 45% based on licensed psychiatric beds, and from about 12% to about 38% based on psychiatric inpatient days. The Herfindahl-Hirschman Index increased from 1700 to about 2590 based on licensed psychiatric beds, and from about 1590 to about 2050 based on psychiatric patient days. HCA, agreed to divest two psychiatric hospitals in the Norfolk, Virginia, metropolitan area, and one general acute care hospital in Midland, Texas,

American Medical International, Inc., 104 F.T.C. 1 (1984) (order modified 104 F.T.C. 20. 617 (1984) and 107 F.T.C. 310 (1986)). The Commission decision held that a for-profit hospital chain's acquisition of a competing hospital in the city and county of San Luis, Obispo, California, violated § 7 of the Clayton Act and § 5 of the FTC Act because the acquisition may substantially lessen competition in the market for general acute care hospital services in that area. The Commission rejected the agreement that the acquisition was exempt from antitrust scrutiny because of the National Health Planning and Resources Act (since repealed). The Commission found that the acquisition lessened both price and nonprice competition, rejecting the argument that there is no price or nonprice competition among hospitals. AMI's acquisition gave AMI control of three of the five hospitals in San Luis Obispo County. As a result of the acquisition, AMI increased its market share from 55.6% to 75.7% in the county market, and from 57.8% to 87% in the city market, measured on the basis of inpatient days (measured on the basis of gross hospital revenues, the figures were 52.2% to 71.3% and 53.3% to 82.4%, respectively, for the county and city markets). The Herfindahl-Hirschman Index increased from 3818 points to 6025 in the county market and from 4370 to 7775 in the city market based on inpatient days (measured on the basis of gross hospital revenues, the figures were 3518 to 5507 and 3996 to 7097, respectively, in the county and city markets). The Commission ordered divestiture of the acquired hospital.

B. Other Hospitals, Health Care Facilities, Providers and Payers

1. Quest Diagnostics Inc. and Unilab Corporation, C-4074 (proposed consent order issued February 21, 2003) (FTC Commission Actions: February 21, 2003 (www.ftc.gov)). The complaint charged that the merger of Unilab, and Quest, two of the largest independent clinical laboratories competing in the market for clinical laboratory testing services in Northern California, would result in prices increases for IPAs, other physician groups, and consumers. Both companies operate patient service centers, full service clinical laboratories and smaller stat (rapid response) laboratories, and together have more than 70% of the clinical laboratory testing services market. According to the complaint, Quest and Unilab compete for contracts to provide laboratory testing services to the patients of physician groups that assume substantial financial risk under capitation arrangements with managed care plans, including providing lab

services to their patients enrolled in the health plans. The proposed order requires that the companies divest to Laboratory Corporation of America 46 patient services centers, 5 stat laboratories, all of Quest's and one of Unilab's contracts with physicians groups in Northern California, and related assets, including customer lists, necessary for the provision of clinical laboratory testing services. In addition, the proposed order contains provisions to ensure the success of the divestiture including the provision of transitional services and incentives for employees to accept employment with Laboratory Corporation of America, and the appointment of an interim monitor.

- 2. Yellowstone Community Health Plan/Blue Cross Blue Shield of Montana, FTC No. 991-0028 (closing letter sent July 14, 1999). This matter involved the merger of Blue Cross Blue Shield of Montana (BCBSMT) and Yellowstone Community Health Plan (Yellowstone), two of the largest health insurers in Montana. The Commission's closing letter stated that although the transaction raised significant antitrust concerns, the Commission closed this investigation in light of conditions placed on the merger by the Montana Insurance Commissioner, in consultation with Commission staff. These conditions included requirements that providers' contracts with the merged entity not prohibit or discourage providers form serving as or contracting with any other health plans, insurers, or HMOs. The conditions also disallowed the sale or transfer of any stock in the joint venture without the written consent of the Commissioner, and required the merged entity to file quarterly reports with the Commissioner.
- 3. <u>Charter Medical Corporation/National Enterprises</u>, 119 F.T.C. 245 (1995) (consent order). The complaint charged that Charter Medical Corporation's (Charter) planned purchase of psychiatric facilities form National Medical Enterprises (NME) would substantially lessen competition for inpatient psychiatric services in four geographic markets, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. Charter and NME are the two largest chains of psychiatric hospitals in the country. According to the complaint, Charter and NME are competitors in the Atlanta, Memphis, Orlando, and Richmond markets, where there are few competitors providing inpatient psychiatric services and entry is difficult due to state certificate of need regulations and other factors.

The order requires Charter to exclude the acquisition of NME's psychiatric facilities in Atlanta, Memphis, Orlando, and Richmond from the acquisition agreement. The order also requires Charter to obtain prior Commission approval before acquiring or selling any psychiatric facilities in those markets for ten years from final Commission approval of the order. Charter's acquisition was allowed to proceed in the other markets.

4. **HEALTHSOUTH Rehabilitation Corp./ReLife Inc.**, 119 F.T.C. 495 (1995) (consent order). The complaint charged that the planned merger of two large rehabilitation hospital

systems, HEALTHSOUTH Rehabilitation Corp. (HEALTHSOUTH) and ReLife Inc. (ReLife), would substantially lessen competition for impatient rehabilitation hospital services in three geographic markets, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. According to the complaint, HEALTHSOUTH and ReLife are competitors in Birmingham, Alabama, Charleston, South Carolina, and Nashville, Tennessee. All three rehabilitation hospital services markets are highly concentrated, and entry is difficult because of state certificate of need regulations.

The order requires HEALTHSOUTH to: 1) divest Nashville Rehabilitation Hospital in Nashville within twelve months; 2) terminate a HEALTHSOUTH management contract to operate a rehabilitation unit at Medical Center East in Birmingham within ninety days; and, 3) terminate a ReLife management contract to operate a rehabilitation unit at Roper Hospital in Charleston by October 1, 1995. HEALTHSOUTH's acquisition was allowed to proceed in the other markets. The order also requires HEALTHSOUTH to obtain FTC approval before it merges any of its rehabilitation hospital facilities with any competing rehabilitation hospital facility in those markets. HEALTHSOUTH also must give the Commission prior notice before carrying out certain joint ventures with competing rehabilitation facilities in the three markets.

5. <u>Columbia/HCA-John Randolph</u>, 120 F.T.C. 949 (1995) (consent order). The complaint alleged that Columbia/HCA's acquisition of John Randolph Medical Center in Hopewell, Virginia would increase Columbia/HCA's market share for psychiatric hospital services in the Tri-Cities (Petersburg and its suburbs) area of Virginia from 50 percent to 70 percent, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. John Randolph Medical Center is a 150-bed general hospital with a 34-bed psychiatric inpatient unit and Columbia owns Poplar Springs Hospital, a psychiatric hospital in Petersburg, Virginia. There is only one other hospital in the area offering psychiatric hospital services and entry is difficult due to state certificate of need regulations.

Under the order, Columbia may acquire John Randolph Medical Center only if it divests Poplar Springs Hospital within twelve months of the Commission's final approval of the order. The order also requires Columbia/HCA to notify the Commission before combining its psychiatric facility with any other psychiatric facility in the Tri-Cities area for ten years from final Commission approval of the order.

6. Columbia/HCA Healthcare Corporation/Medical Care America, 118 F.T.C. 1174 (1994) (consent order); 126 F.T.C. 181 (1998) (modifying order substituting a prior notice provision for the prior approval requirement). The complaint charged that the merger of Columbia/HCA Healthcare Corporation and Medical Care America may substantially lessen competition in the market for outpatient surgical services in the Anchorage, Alaska area, in

violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. Columbia, a large for-profit hospital chain, and Medical Care America, a large ambulatory surgical center chain, both had facilities in Anchorage. According to the complaint, Columbia operated a hospital in Anchorage which competed with Medical Care America's ambulatory surgical facility in that city, Alaska Surgery Center. The complaint further alleged that the market for outpatient surgical services in Anchorage was highly concentrated, and that entry is difficult. Finally, the complaint alleged that the merger may substantially lessen competition by significantly increasing the already high level of concentration in the market, and enhancing the possibility of collusion or interdependent coordination by the remaining firms in the market.

Under the order, Columbia was required to divest the Alaska Surgery Center within twelve months after the order became final, to a purchaser approved by the FTC. Columbia was also required to hold the Alaska Surgery Center separate from its other operations, and to maintain its marketability and viability as an independent competitor in the market until the divestiture is completed. For a period of ten years, the required Columbia to receive prior Commission approval before either acquiring another outpatient surgical facility in Anchorage, or transferring an outpatient surgical facility to anyone operating another outpatient surgical facility in Anchorage. In addition, for a period of ten years, the acquirer of Alaska Surgery Center must obtain Commission approval before selling the facility in Anchorage.

7. <u>Hospital Corporation of America</u> (See Section IV A for citation and annotation.)

V. INDUSTRY GUIDANCE STATEMENTS

A. Statements of Antitrust Enforcement Policy in Health Care

On September 15, 1993, the Federal Trade Commission and the Department of Justice jointly issued six policy statements containing "safety zones" for provider conduct that the agencies generally would not challenge under the antitrust laws. These statements reflected prosecutorial standards based on the agencies' previous advisory opinions, case law, and experience with respect to the covered activities. The policy statements were updated and expanded on September 27, 1994, when the agencies issued nine statements of enforcement policy and analytical principles. Seven of the statements contained safety zones, and two statements described the agencies' analytical process for analyzing certain health care activities. On August 28, 1996, in response to changes in the health care market, the agencies issued revisions to statements eight and nine concerning physician network joint ventures

and multiprovider networks.4

- 1. <u>Mergers</u>. Except in extraordinary circumstances, the Commission will not challenge mergers of general hospitals where one hospital has fewer than 100 beds, fewer than 40 patients a day, and is more than five years old.
- 2. <u>High Tech Joint Ventures</u>. Except in extraordinary circumstances, the Commission will not challenge joint ventures among hospitals to purchase, operate and market high-technology or other expensive medical equipment, that involve only the number of hospitals necessary to support the equipment. If more than the minimum number of hospitals are included in the venture, but the additional hospitals could not support the equipment on their own or through a competing joint venture, the agencies will not challenge the venture. Neither the FTC nor the Justice Department has challenged an integrated joint venture to provide such services.
- 3. Joint Ventures Involving Specialized Clinical or other Expensive Health Care Services. The statement explains how the agencies will analyze hospital joint ventures to provide specialized clinical or other expensive health care services. Under a "rule-of-reason" analysis, the agencies define the relevant market, weigh any anticompetitive effects against any procompetitive efficiencies generated by the venture, and examine whether collateral restraints, if any, are necessary to achieve the efficiencies sought by the venture. The statement does not include a safety zone for such ventures, because the agencies believe that they must acquire more expertise in evaluating the cost of, demand for, and potential benefits from such joint ventures before they can articulate a meaningful safety zone. Neither the FTC nor the Justice Department has challenged an integrated joint venture to provide such services.
- 4. <u>Information Sharing</u>. Except in extraordinary circumstances, the Commission will not challenge the collective provision by health care providers of medical information to help purchasers of their services resolve issues about the mode, quality or efficiency of medical treatment. Thus, the FTC would not object to a medical society collecting outcome data from its members about a particular procedure, and then providing that information to purchasers. Nor would the FTC challenge the development of suggested standards for clinical patient care by physicians. This safety zone does not protect provider conduct to coerce compliance with recommendations, and does not cover the collective provision of fee-related information to purchasers.

⁴ Statements of Antitrust Enforcement Policy in Health Care, issued on August 28, 1996, 4 Trade Reg. Rep. (CCH) ¶13,153; Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust, issued on September 27, 1994, 4 Trade Reg. Rep. (CCH) ¶13,152; and Department of Justice and Federal Trade Commission Antitrust Enforcement Policy Statements in the Health Care Area, issued on September 15, 1993, 4 Trade Reg. Rep. (CCH) ¶13,151. The 1996 Policy Statements are available at the FTC's web site.

- 5. Information Collection. Except in extraordinary circumstances, the Commission will not challenge health care providers' collective provision of current or historical, but not prospective, feerelated information to health care purchasers, as long as the activity meets conditions designed to ensure that providers cannot share the information among themselves to coordinate prices or engage in other conduct that harms consumers. Collection of the information must be managed by a third party. Any information that is shared among the providers generally must be more than three months old and it must be based on information from at least five providers; no one provider's data can represent more than 25 percent of the statistic; and the data must be aggregated so recipients cannot identify the prices charged by an individual provider. The policy statement goes on to caution that such collective provision of fee-related information by competing providers may not involve joint negotiation of, or agreement on, price or other competitively-sensitive terms by the health care providers, or involve any coercive collective conduct.
- 6. **Price Surveys**. Except in extraordinary circumstances, the Commission will not challenge participation by competing providers in surveys of prices for hospital services, or salaries, wages, or benefits of hospital personnel, under certain conditions designed to ensure the data is not used to coordinate prices or costs. To satisfy these conditions, the survey must be managed by a legitimate third-party; the data provided by hospitals must be more than three months old; and at least five hospitals must report the data on which each statistic is based. No one hospital's data can represent more than 25 percent of the statistic, and the survey results must be sufficiently aggregated to make it impossible to determine the prices or compensation for any particular hospital.
- 7. **Purchasing Arrangements**. Except in extraordinary circumstances, the Commission will not challenge joint purchasing arrangements among health care providers, as long as they meet conditions designed to ensure they do not become vehicles for monopsonistic purchasing or for price fixing. To fall within this safety zone, the purchases made by the health care providers must account for less than 35 percent of the total market for the purchased items; and for joint purchasing arrangements including direct competitors, the cost of the purchased items must account for less than 35 percent of the total market for the purchased items, and the cost of the purchased items must account for less than 20 percent of the total revenues of each purchaser.
- 8. Physician Network Joint Ventures. The revised statement on physician network joint ventures provides an expanded discussion of the antitrust principles that apply to such ventures. The statement explains that where physicians' integration through the network is likely to produce significant efficiencies, any agreements on price reasonably necessary to accomplish the venture's procompetitive benefits will be analyzed under the rule of reason. The revisions focus on the analysis of networks that fall outside the safety zones, particularly those networks that do not involve the sharing of substantial financial risk by their physician participants. The safety zones for physician network joint ventures (exclusive physician network joint ventures comprised of no more than 20 percent of the physicians in

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any specialty in a geographic market who have active hospital staff privileges and who share substantial financial risk; non-exclusive physician network joint ventures comprised of no more than 30 percent of the physicians in each specialty in a geographic market who have active staff privileges and who share substantial financial risk) remain unchanged, but the revised statement identifies additional types of financial risk-sharing arrangements that can qualify a network for the safety zones. The statement adds three hypothetical examples to show how the agencies will apply the antitrust laws to specific situations.

9. Multiprovider Networks. Multiprovider networks are ventures among providers to jointly market their services to health benefits plans and others. Because multiprovider networks involve a large variety of structures and relationships among many different types of health care providers, the agencies are unable to set out a safety zone. The 1996 statement explains that multiprovider networks will be evaluated under the rule of reason, and will not be viewed as per se illegal if the providers' integration through the network is likely to produce significant efficiencies that benefit consumers, and if any price agreements by the networks are reasonably necessary to realize those efficiencies. The revised statement gives examples of arrangements through which financial risk can be shared among competitors in a multiprovider network, but does not foreclose other possibilities. Many of the revisions to this statement reflect changes made to the revised statement on physician network joint ventures. The statement also sets forth four hypothetical examples of how the agencies will apply the antitrust laws to specific situations involving multiprovider networks.

B. 1981 Commission Policy Statement

Federal Trade Commission, Enforcement Policy with Respect to Physician

Agreements to Control Medical Prepayment Plans, 46 Fed. Reg. 48,982 (1981). The

Commission Statement sets forth enforcement policies in connection with physician control of
prepayment plans. Under the Commission's policy, physicians' control of a prepayment plan will raise
antitrust concerns when formation or operation of the plan eliminates potential competition or reduces
competition among physicians or competing plans – for example, where a plan with significant market
power artificially inflates fees, unreasonably excludes certain types of providers from coverage, or
prevents the formation of competing plans.

C. Advisory Opinions

Under the statements, the Commission has committed to responding within 90 days to requests for advice from health care plans or providers about matters addressed by the "safety zones" or the non-merger policy statements; and within 120 days to requests for advice regarding multiprovider networks and other non-merger health care matters. The response period will commence once all necessary information has been received by the Commission.

Information regarding advisory opinions is set forth in the Topic And Yearly Indices of Health Care Advisory Opinions By Commission And By Staff. The index and the text of the advisory opinions issued since October, 1993, are available at the FTC's web site at http://www.ftc.gov.

D. Citizen Petition to the Food and Drug Administration

The Bureau of Competition and the Policy Planning Staff of the Federal Trade Commission submitted a Citizen Petition to the Commissioner of Food and Drugs on May 16, 2001, in which it requested guidance on the FTC staff's interpretation of certain FDA regulations related to patent listings in the Orange Book. The petition sought the FDA's views on the two prong criteria that a patent must meet under 21 C.F.R. § 314.53 (b) before it can be listed in the Orange Book. The petition also asked for guidance on other patent listing issues, including whether an NDA holder can list a patent for an unapproved aspect of an approved drug, or a chemical compound not approved for use as the drug substance in an approved drug product, and the meaning of the term "drug product" as it relates to infringement analysis under the regulation. FDA never formally responded to our citizen's petition, but instead issued proposed regulations on October 24, 2002, to modify in part its regulations concerning Orange Book listings. Staff submitted comments to the proposed regulations on December 23, 2002. FDA's proposed regulations remain pending.

VI. AMICUS BRIEFS

2. Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpham's Cross Motion for Entry of An Amended Order in Smithkline Beecham Corporation v. Apotex Corporation, Case No. 99-CV-4304 (E.D. Pa., January 29, 2003); (FTC Commission Actions: January 29, 2003 (www.ftc.gov). Smithkline Beecham (now GlaxoSmithKline) sued Apotex, a generic drug manufacturer, for infringing two patents on it's antidepressant drug Paxil. After the district court ruled the Glaxo patents invalid, Apotex filed a motion to have the two patent listings removed from the Orange Book. In response to this motion, the Commission filed an amicus brief arguing that improper listings in the Orange Book effect competition and harm consumers. The Commission detailed the anticompetitive effects resulting from improper listings, including additional 30-month stays of FDA approval, that ultimately delay the entry of generic drugs. The Commission also argued that consumers benefit from the large savings that result from the competition provided by generic drugs, an estimated \$30 million dollars a month in the case of a generic Paxil. The Commission argued that a delisting remedy is consistent with the Court's judgment of invalidity, because it would prevent the branded manufacturer from benefitting from the 30-month stay of FDA approval even after a judgment of invalidity.

- 2. Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss in In re: Buspirone Patent, Antitrust Litigation, 185 F. Supp. 2d 363 (S.D. N.Y. 2002); (FTC Commission Actions: January 9, 2002) (www.ftc.gov). The In re: Buspirone Patent and Antitrust Litigation involves claims by generic drug manufacturers that Bristol-Myers-Squibb, manufacturer of the brand drug BuSpar, attempted to delay generic competition to BuSpar, in violation of Section 2 of the Sherman Act, when it filed misrepresentative claims to the FDA concerning the listing of a newly issued patent in the Orange Book. BMS filed a motion to dismiss the case on the grounds that the listing is valid petitioning to a government agency and therefore immune from the antitrust laws under Noerr. In its amicus brief, the Commission argued that Orange Book filings are not immune from Sherman Act liability under *Noerr* because: 1) they are ministerial filings and not legitimate petitions intended to influence governmental decision-making; 2) they do not constitute adversarial pre-litigation threat letters incidental to litigation, and 3) they are not necessary for patent infringement litigation. The Commission also argued that even if the Orange Book listings constitute "petitioning" under *Noerr*, the misrepresentation and sham exceptions may deprive BMS of *Noerr* immunity. The court ruled that the listing of the buspirone patent in the Orange Book was not valid petitioning of a government agency and therefore not protected under *Noerr*; in addition, according to the court, the plaintiffs had shown that there was reason to warrant an exception to *Noerr* immunity because BMS had obtained the patent fraudulently and attempted to maintain a monopoly by bringing the patent litigation.
- Brief of the Federal Trade Commission as Amicus Curiae in American Bioscience, Inc. 3. v. Bristol-Myers Squibb Co., No. CV-00-08577 WMB (AJWx) (C.D. Cal., September 1, 2000); (FTC Commission Actions: September 1, 2000 (www.ftc.gov)). American Bioscience, Inc. (ABI) sued Bristol-Myers Squibb, the maker of Taxol, a drug used to treat cancer, to force it to list a patent on the FDA Orange Book, and obtained an unopposed temporary restraining order (TRO). As part of a proposed settlement between ABI and Bristol, the parties agreed that (1) the court would enter a finding that ABI's patent should be listed in the Orange Book, and (2) Bristol would maintain the listing of the patent in the Orange Book. In its amicus brief, the Commission asked the judge to consider the anticompetitive ramifications of the proposed settlement. First, another court might find any judicial finding that the patent met the statutory requirements for listing on the Orange Book persuasive, or even conclusive, thus hindering a generic company's attempt to challenge the listing. Second, the order to maintain the listing would conflict with any later court order requiring Bristol to delist the patent, and resolving the conflicting court orders could further forestall generic entry. The brief also announced the Commission's investigation of ABI and Bristol, and asked the court to consider its pendency when deciding on the proposed settlement. The court ultimately determined that ABI could not maintain a private action under the Food, Drug, and Cosmetics Act, dissolved the TRO, and ordered Bristol to delist the ABI patent.

- 4. Brief for the United States and the Federal Trade Commission as Amici Curiae in Support of Suggestion of Rehearing En Banc, Supplemental En Banc Brief for the United States and the Federal Trade Commission as Amici Curiae urging reversal in support of Appellant, Surgical Care Center of Hammond v. Hospital Service Dist. No. 1 of Tangipahoa Parish, 153 F.3d 220 (5th Cir. 1998); reh'g granted en banc, 162 F.3d 294 (5th Cir. 1998); rev'd and remanded, 171 F.3d 231 (5th Cir. 1999), cert denied, 120 S. Ct. 398 (1999). An outpatient surgical center sued a Louisiana hospital service district alleging anticompetitive activity in violation of Section 2 of the Sherman Act that included signing exclusive contracts with five managed care plans. The district court and a panel of the Fifth Circuit concluded that the hospital district, as a state political subdivision, was entitled to state action immunity because the conduct was a foreseeable result of the state statutory scheme which authorizes hospital districts and specifies their powers and duties. The Department of Justice and Commission filed an amicus brief in support of a rehearing en banc, and later a supplemental amicus brief on the merits in support of reversal, arguing that state action immunity protects state subdivisions only when there is a clearly articulated state policy to displace competition. The briefs also argued that the panel's ruling held conduct immune from the Sherman Act and gave the hospital district, in the absence of a state policy to displace competition, special license to violate the antitrust laws. The en banc court ruled unanimously that the state legislature did not make sufficiently clear its intent to insulate the hospital district from the constraints of the Sherman Act, reversed the panel's ruling and remanded the case back to the district court. The Supreme Court denied the defendant's petition for certiorari on November 1, 1999.
- 5. Brief for the United States and the Federal Trade Commission as Amicis Curiae in Ertag v. Naples Community Hospital, No. 92-341-CIV-FTM-25D, slip op. (M.D. Fla., July 31, 1995); No. 95-3134 (11th Cir.). In a case where neurologists alleged that a hospital violated the federal antitrust laws by restricting the official interpretation of MRI scans to radiologists, the district court granted summary judgment for the defendant hospital on the ground that the complaining neurologists lacked standing under Todorov v. DCH Healthcare Auth., 921 F.2d 1438 (11th Cir. 1991), because they could not show antitrust injury nor were they efficient enforcers of antitrust law. The Commission and the Justice Department filed an amicus brief arguing that Todorov did not establish a general rule barring suits by excluded competitors. The brief also argued that a general rule denying standing to excluded competitors whenever there is a possibility consumers or the government could sue is inconsistent with Supreme Court precedent. In an unpublished decision on August 1, 1997, the Eleventh Circuit reversed the district court decision, ruling that the district erred in concluding that the neurologists lacked standing to assert their antitrust claims.
- 6. Brief for the United States and the Federal Trade Commission as Amici Curiae in Support of Petition for Rehearing, <u>Blue Cross and Blue Shield United of Wisconsin v.</u>

Marshfield Clinic, 65 F.3d 1406 (7th Cir. 1995), cert. denied, 116 S. Ct. 1288 (1996). A health insurer filed an antitrust suit against a clinic, claiming that the clinic had monopolized the market for HMOs and engaged in various anticompetitive agreements. The Commission and Justice Department filed an amicus brief in support of a petition for rehearing, asking that the court modify its opinion on the subject of whether HMOs constitute an antitrust market, and whether "most favored nations" provisions may be anticompetitive. The Court modified its decision by adding statements that its rulings on these two issues were based upon and related only to the facts in the immediate case. In all other respects, the court denied the petition for rehearing.

- 7. Brief of the Federal Trade Commission as Amici Curiae on Appeal from United States District Court, Nurse Midwifery Associates v. Hibbett, (See Section II C for citation and annotation.)
- 8. Brief of the Federal Trade Commission as Amici Curiae on Appeal from United States District Court, Parker v. Kentucky Board of Dentistry, (See Section II D for citation and annotation.)
- 9. En Banc Brief of the Federal Trade Commission as Amicus Curiae on Appeal from United States District Court, Bolt v. Halifax Hospital Medical Center, appealing 851 F.2d 1273 (11th Cir. 1988), vacated, reh'g granted en banc, 861 F.2d 1233 (11th Cir. 1988), remanded to panel, 874 F.2d 810 (11th Cir. 1990), cert. denied, 109 L. Ed. 322 (1990). In an antitrust action brought by a vascular and general surgeon, whose medical staff privileges had been revoked at three hospitals, against the hospitals, members of their medical staffs, and the local medical society, at issue was whether the "active supervision" component of the state action doctrine was satisfied by the availability of common law judicial review. In its amicus brief, the Commission argued that the Eleventh Circuit Court panel had previously erred in holding that "active supervision" was met by common law judicial review, which entailed consideration of the fairness of the procedures used by the private parties, the validity of the private decision makers' criteria under state law, and the sufficiency of the evidence. The Commission stated that even if Florida courts in fact provided sufficient review to meet the panel's standard, that standard would not satisfy the standard set forth by the Supreme Court in Patrick v. Burget, 486 U.S. 94 (1988), for "active supervision" – that the state undertake a thorough, on-the-merits review of individual private decisions to determine whether that conduct is in accordance with state policy. The en banc court ruled that the appellee hospitals and their medical staffs waived at oral argument any claim to state action immunity. The court reinstated the panel opinion in 851 F.2d 1273, with the exception of the discussion of the state action exemption, which remains vacated. Approximately one month later, a panel of the 11th Circuit held, in Shahawy v. Harrison, 875 F.2d 1525 (11th Cir. 1989), that judicial review of

hospital privilege decisions did not meet the standards for active supervision set forth by the Supreme Court in <u>Patrick</u>.

- 10. Brief of the United States and Federal Trade Commission as Amici Curiae on Petition for Writ of Certiorari, and Brief of the United States and Federal Trade Commission as Amicus Curiae on Writ of Certiorari, Patrick v. Burget, 486 U.S. 94 (1988). A jury verdict in favor of a physicians who had alleged bad faith termination of staff privileges by physicians and a hospital in violation of the antitrust laws was reversed by the Ninth Circuit, which held that the defendants' action was protected by the state action doctrine because state law required hospitals to conduct peer review to promote quality of care. The Department of Justice and Commission filed an amicus brief supporting certiorari, and later an amicus brief on the merits in support of reversal, arguing that the state action doctrine did not immunize the challenged conduct from antitrust liability because there was no state supervision of that conduct. The Supreme Court reversed the Ninth Circuit on this issue.
- 11. **Brief of the Federal Trade Commission as Amicus Curiae on Appeal from United States District Court, Bhan v. NME Hospitals, Inc.**, 772 F.2d 1467 (9th Cir. 1985). In a nurse anesthetist's suit challenging a hospital's policy of allowing only physician anesthesiologists to perform anesthesia services in the hospital's operating rooms, the Commission filed an amicus brief arguing for reversal of the district court's dismissal of the case based on that court's reasoning that physician anesthesiologists and nurse anesthetists did not compete. The Commission argued that California law does not preclude competition between the two groups, and that the district court's finding was contrary to established precedent and the premises of antitrust law. The Ninth Circuit reversed the district court on this issue.
- Brief of the Federal Trade Commission as Amicus Curiae, Lombardo v. Our Lady of Mercy Hospital, No. 85-2474 (7th Cir. Amicus brief filed Nov. 7, 1985), appeal dismissed, (appealing Lombardo v. Sisters of Mercy Health Corp., 1985-2 Trade Cases (CCH) ¶66,749 (N.D. Ill. 1985). In a case brought by two osteopathic physicians charging that an Indiana hospital's denial of staff and surgical privileges violated federal and state antitrust laws, the Commission filed an amicus brief arguing that the state action doctrine would not protect from antitrust scrutiny the denial of privileges and the participation of private physicians in adopting and implementing the hospital policy excluding osteopathically-trained surgeons. The Commission argued that neither of the two requirements for state action a clear articulation of an intention to supplant competition or active state supervision was met under the relevant statute which required hospitals to have peer review systems and hospital privilege review mechanisms.
- 13. Brief of the Federal Trade Commission as Amicus Curiae on Appeal from United

States District Court, North Carolina ex rel. Edmisten v. P.I.A. Asheville, Inc., 722 F.2d 59 (4th Cir. 1983), cert. denied, 471 U.S. 1003 (1985). The Attorney General of North Carolina brought suit alleging that the acquisition of a private psychiatric hospital by a hospital system, which would result in the system's ownership of all the private psychiatric hospitals within the area served by the Western North Carolina Health Systems Agency, violated the federal and state antitrust laws. The Commission and Department of Justice filed an amicus brief arguing that the National Health Planning Act and the state statute adopted pursuant to that Act did not impliedly repeal the antitrust laws, because there was no "plain repugnancy" between the regulatory scheme and the antitrust laws. They also argued that the defendants' activities were not exempt from antitrust scrutiny under the state action doctrine. The Fourth Circuit held that antitrust immunity was implied by the legislative history and regulatory structure of the Act.

- 14. Brief of the United States and Federal Trade Commission as Amici Curiae on Petition for Writ of Certiorari, <u>Jefferson Parish Hospital District No. 2 v. Hyde</u>, (See Section II F for citation and annotation.)
- 15. Brief of the United States and Federal Trade Commission as Amici Curiae on Petition for Writ of Certiorari, Trustees of Rex Hospital v. Hospital Building Co., 464 U.S. 890 and 904 (1983) (denying writ of certiorari). In an antitrust suit brought by a hospital operator alleging a conspiracy by other hospital operators to prevent the plaintiff from expanding its hospital facilities, the Commission and Department of Justice filed an amicus brief in support of the petition for certiorari, arguing that the Court of Appeals had erred in creating a special rule-of-reason standard under the Sherman Act for evaluating the actions of private health care providers who had attempted to block the construction or expansion of competing hospital facilities through the certificate-of-need (CON) process. The Department of Justice and Commission argued that the rule of reason analysis adopted by the lower court might improperly protect abuse of the CON process by hospital competitors.

VII. INDICES

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